BAYER CROPSCIENCE LP AND NICHINO AMERICA, INC.
MOTION FOR ACCELERATED DECISION

EXHIBIT LIST

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8.	Letter from Lois Rossi (EPA Registration Division) re Preliminary Acceptance of Flubendiamide Registrations (July 31, 2008)
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19.	EPA Press Release, EPA Moves to Cancel the Insecticide Flubendiamide (Mar. 1, 2016)
20.	Flubendiamide; Notice of Intent to Cancel Pesticide Registrations, 81 Fed. Reg. 11,558 (Mar. 4, 2016)
21.	EPA BEAD Public Interest Finding for Flubendiamide (Apr. 15, 2008)
22.	Bayer CropScience LP, A Benefits Document Supporting the Continued Registration of Flubendiamide (May 20, 2015)
23.	EPA BEAD Review of Bayer CropScience LP Flubendiamide Benefits Document (July 24, 2015)
24.	Bayer CropScience LP, White Paper: Flubendiamide Benefits, Aquatic Risk Assessment Summary and Proposed Path Forward (June 29, 2015)
25.	EPA EFED Response to Bayer CropScience LP White Paper (July 15, 2015)
26.	Letter from Jerry Baron (IR-4) re Comments on Flubendiamide Notice of Intent to Cancel (Mar. 28, 2016)
27.	EPA EFED Risk Assessment for the Section 3 New Chemical Registration of Flubendiamide (June 23, 2008)
28.	EPA EFED Risk Assessment for Legume Vegetable and Christmas Tree New Uses for the Insecticide Flubendiamide (May 17, 2010)
29.	EPA EFED Ecological Risk Assessment for the New Use of Flubendiamide on Alfalfa and Certain Other Crops (Dec. 16, 2010)
30.	EPA Decision Memorandum for Flubendiamide Cancellation (Jan. 29, 2016)
31.	EPA EFED Flubendiamide Ecological Risk Assessment Addendum (Jan. 28, 2016)
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Exhibit Number	Description
33.	Des-iodo Spiked Water Study Data Evaluation Record (May 21, 2008)
34.	Des-iodo Spiked Sediment Study Data Evaluation Record (July 19, 2011)
35.	EPA EFED Review of Three Reports re Three-Year Flubendiamide Water Monitoring Project (Feb. 20, 2015)
36.	EPA EFED Response to Bayer CropScience LP Aquatic Risk Email Submission (July 8, 2015)
37.	Ames Herbert Curriculum Vitae
38.	D. Ames Herbert, Jr., and Sean Malone, Mid-Atlantic Guide to the Insect Pests and Beneficials of Corn, Soybean and Small Grains (Virginia Integrated Pest Management, Virginia Cooperative Extension Publication 444-360, 2d ed. 2011)
39.	2016 Insect Control Guide For Agronomic Crops (Mississippi State University Extension Publication 2471, 2016)
40.	Ames Herbert, Virginia Soybeans: Pyrethroid Resistance Hits High Levels, So Understand Treatment Options (AgFax Aug. 20, 2012)
41.	United States Department of Agriculture, Preventing or Mitigating Potential Negative Impacts of Pesticides on Pollinators Using Integrated Pest Management and Other Conservation Practices, Agronomy Technical Note No. 9 (Feb. 2014)
42.	D. Ames Herbert, Jr., and Michael Flessner, Pest Management Guide Field Crops 2016 (Virginia Cooperative Extension Publication 456-016, 2016)
43.	Dwayne Moore Curriculum Vitae
44.	EFED Memorandum re Toxicity Testing and Ecological Risk Assessment Guidance for Benthic Invertebrates (Apr. 10, 2014)
45.	OECD Guidelines for the Testing of Chemicals, Test No. 219: Sediment-Water Chironomid Toxicity Test Using Spiked Water (Apr. 13, 2004)
46.	OECD Guidelines for the Testing of Chemicals, Test No. 218: Sediment-Water Chironomid Toxicity Test Using Spiked Sediment (Apr. 13, 2004)
47.	European Commission, Working Document: Guidance Document on Aquatic Toxicology (Oct. 17, 2002)

Exhibit Number	**Description**
48.	OECD Series on Testing and Assessment No. 54: Current Approaches in the Statistical Analysis of Ecotoxicity Data: A Guidance to Application (Excerpts) (May 9, 2006)
49.	EPA EFED Preliminary Environmental Fate and Ecological Risk Assessment for Methoxyfenozide (Excerpts) (Sept. 16, 2015)
50.	Bernard Engel Curriculum Vitae
51.	EPA, Guidance on the Development, Evaluation, and Application of Environmental Models (Mar. 2009) (Excerpts)
52.	Existing Stocks of Pesticide Products; Statement of Policy, 56 Fed. Reg. 29,362 (June 26, 1991)
53.	Intervenor's Response to Respondents' Motion for Voluntary Vacatur and Remand, Dkt. #122, *NRDC v. EPA*, No. 14-73353 (9th Cir.) (Dec. 7, 2015)
54.	Remand Order, Dkt. #128, *NRDC v. EPA*, No. 14-73353 (9th Cir.) (Jan. 25, 2016)
55.	EPA's Conditional Opposition to CropLife America's Motion to File an Amicus Curiae Brief, Dkt. #24, *In re Reckitt Benckiser*, EPA FIFRA Docket No. 661 (May 6, 2013)

EXHIBIT 1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of:	)	
	)	
Bayer CropScience LP and	)	FIFRA-HQ-2016-0001
Nichino America, Inc.,	)	
	)	
Petitioners.	)	

DECLARATION OF LEE HALL
IN SUPPORT OF MOTION FOR ACCELERATED DECISION

I, Lee Hall, hereby declare as follows:

I. PROFESSIONAL BACKGROUND

1. I currently serve as Industry Relations Lead for Bayer CropScience LP ("Bayer"). In that role I work with stakeholders in various commodity, grower, trade organizations and other stakeholder groups.

2. I have worked in the pesticides industry for nearly 32 years. I joined Union Carbide Agricultural Products Company (a legacy company of Bayer) in May 1984. My experiences at Bayer have included 26 years in various roles in R&D including Discovery Research, Field Research, Technical Service and Product Development. I served as a Product Manager for 8 years before transitioning to my current position in Regulatory as Industry Relation Manager. In that role I was responsible for Broad Acre Insecticides and Nematicides, including flubendiamide brands.

3. As Product Manager I was responsible for Bayer's flubendiamide products from their launch in 2008 until April of 2015. I continue to be involved in flubendiamide, focusing on growers' needs and product usage issues in my current role as Industry Relations Lead.

II. DEVELOPMENT OF FLUBENDIAMIDE

4. Bayer is a world-leading innovator in the development of newer, more effective, and more sustainable crop protection products. Bayer's U.S. business headquarters is located in Research Triangle Park, North Carolina.

5. Bayer's mission of Science for a Better Life is to provide products that help farmers feed a growing population and foster healthy environments. This mission is supported by the discovery, development, registration, marketing, and stewardship of safe, effective, and environmentally responsible plant protection technologies.

6. Flubendiamide is the first pesticide in its class of chemistry, known as phthalic acid diamides, to be registered by EPA under FIFRA. Flubendiamide is approved for use on over 200 crops and provides excellent, targeted control of larval lepidopteran pests (caterpillars). Flubendiamide is consistent with and furthers the goals of modern Integrated Pest Management ("IPM") practices and is an important tool for resistance management.

7. Flubendiamide was invented by Nihon Nohyaku Co., Ltd. ("NNC"). Bayer has a licensing, product development, and marketing agreement with NNC and Nichino pursuant to which Bayer serves as Nichino's regulatory agent for flubendiamide and sells flubendiamide products under the Belt® brand name. As regulatory agent, Bayer took the lead on engaging in discussions with EPA and generating data required to support the flubendiamide registrations. Nichino sells flubendiamide products under the Vetica® and Tourismo® brand names.

8. Bayer and Nichino ("Registrants") are the original and current holders of the flubendiamide registrations that are the subject of EPA's proposed cancellation. Bayer holds the registration for the Belt® SC Insecticide end-use product (EPA Reg. No. 264-1025). Nichino holds the registration for the Flubendiamide Technical product (EPA Reg. No. 71711-26), which consists of nearly pure flubendiamide and is used to manufacture end-use products, and the

Vetica® Insecticide and Tourismo® Insecticide end-use product registrations (EPA Reg. Nos. 71711-32 and 71711-33), which combine flubendiamide with buprofezin, another insecticide.

9. Bayer invests heavily in the expertise needed to design and conduct the complex health and environmental tests and analyses necessary to obtain and maintain EPA pesticide approvals. Bayer has made significant investments to obtain and maintain the flubendiamide registrations. Bayer spent more than $60 million in data and development costs to obtain the initial registrations and to support the expansion and continuation of the registrations.

III. FLUBENDIAMIDE USE AND BENEFITS

A. Product Use

10. Flubendiamide provides excellent, targeted control of larval lepidopteran pests (caterpillars) by affecting certain receptors in the targeted species, stopping feeding within minutes.

11. Flubendiamide products are sold by Bayer and Nichino throughout the country, with their primary use running across the South and up the West Coast (south of the Mason-Dixon line and from Virginia through California).

12. Flubendiamide was originally labeled for use on broad acre crops (e.g., corn and cotton), pome fruit, tree nuts, vines, and some vegetables. Over time, EPA has expanded the approved uses to cover more than 200 crops.

13. Growers use flubendiamide on a wide range of crops throughout the year. It is used on winter vegetables in Arizona and Florida from January through March, on tree fruits and nuts in California from March through June, on soybeans, cotton, and alfalfa from June through August, and on fall vegetables from September through December.

B. Benefits of Flubendiamide

14. Registrants submitted to EPA in May of 2015 a comprehensive summary of flubendiamide's human health, environmental, safety, and pest management benefits across fifteen representative crops, complete with citations to articles published in scientific journals, field study results, and crop-specific testimonials from growers, grower organizations and experts in the field of entomology. This submission included over 300 pages of comparative health and safety information, use information, and third party data, articles, and letters of support demonstrating flubendiamide's current use and benefits and its important current and future role for IPM and resistance management. Exhibit 22. Bayer supplemented that submission with a White Paper in June 2015. Exhibit 24.

15. As outlined, below, while Flubendiamide is not a high volume use product, but where it is used, the qualitative benefits are significant.

1. Minimal Impact on Beneficial Insects

16. As EPA has acknowledged, because flubendiamide is selective, it has minimal impact on beneficial insects, including parasitic and predatory species such as parasitoid wasps, ladybird beetles, and syrphid flies. Exhibit 23 at 4 (BEAD Review of Bayer CropScience Flubendiamide Benefits Document (July 24, 2015)). This encourages natural or biological pest control, and makes flubendiamide an important tool for modern IPM approaches. IPM is an ecosystem-based strategy that focuses on long-term prevention using a range of practices to minimize negative impacts and resistance issues.

17. In its 2008 Public Interest Finding EPA described flubendiamide as a "novel chemistry" with "low toxicity to insect predators and honey bees [that] should make flubendiamide an important component in integrated pest management programs." Exhibit 21 at 1, 6 (BEAD Public Interest Finding for Flubendiamide (Apr. 15, 2008)).

18. By contrast, broader-spectrum alternatives like pyrethroids, organophosphates, and carbamates affect a much wider range of insects, including beneficial species. Broad-spectrum pesticides can cause flare-ups when populations of fast-reproducing species, such as aphids and mites, recover and grow unchecked in the absence of slower-reproducing insect predators. These flare-ups can create new pest problems that require additional pesticide applications with additional environmental impacts and increased costs to the growers. Flubendiamide's selectivity and minimal impact on predatory insects help avoid these problems.

2. Managing Resistance

19. Flubendiamide products are also an important tool for growers in managing pest resistance. They can be rotated (i.e., alternated) with other pesticides with different modes of action as part of a resistance management program to avoid resistance issues that can arise from the overuse of a single mode of action. As a member of the diamide class of chemistry, flubendiamide has a different mode of action from pyrethroids, carbamates, and organophosphates and is effective at controlling insect populations that have developed resistance to those classes of chemistry.

20. EPA agrees that cancellation of flubendiamide would "reduce[] the ability to manage" insecticide resistance and that likely alternatives including pyrethroids "do not fit well with most IPM practices." Exhibit 23 at 8.

21. Also, unlike chlorantraniliprole, its main IPM-friendly alternative, flubendiamide is non-systemic. This is significant because prolonged pest exposure to systemic insecticides, which can expose multiple generations of pests, has resulted in the development of resistance by some insects to those products.

3. Safety and Risk Profiles

22. Flubendiamide has an excellent safety profile compared to alternatives such as organophosphates, carbamates, and pyrethroids. As EPA acknowledges, flubendiamide poses no risk of concern to humans (either through diet or worker exposure), fish, mammals, crustaceans, mollusks, beneficial insects, and plants. *See*, *e.g.*, Exhibit 9 at 2-8 (EPA Flubendiamide Pesticide Fact Sheet (Aug. 1, 2008)). Growers prefer pesticides that they can be confident do not pose any health or safety risk to themselves or their employees.

23. Furthermore, on August 12, 2015, Bayer submitted an additional benefits analysis comparing flubendiamide to two well-known alternative pesticides. Both alternative chemicals pose significantly greater risk to aquatic invertebrates than flubendiamide. This assessment demonstrated that partial or full market share substitution from flubendiamide to these alternative pesticides would increase the immediate risk to aquatic invertebrates. EPA has not provided any specific response to this assessment.

24. In addition to its safety benefits, flubendiamide's lower risk profile allows for more flexible use because of fewer restrictions on timing of application (e.g., shorter pre-harvest intervals and restricted entry intervals for workers).

4. Commercial Benefits

25. Flubendiamide is a competitively priced "IPM friendly" insecticide, and for certain crops is less than half the cost of chlorantraniliprole, its major phthalic diamide competitor. EPA has acknowledged flubendiamide's competitive pricing compared to IPM alternatives such as chlorantraniliprole. Exhibit 23 at 6.

26. Unlike many of the other products commonly used to control lepidopteran insects, flubendiamide products are rainfast once spray deposits have dried, providing control for up to

two weeks. Flubendiamide's residual effectiveness period can reduce the need for multiple applications, lowering costs and environmental impacts.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this _11th___ day of ______April_________, 2016

Lee Hall

EXHIBIT 2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of:	)	
	)	
Bayer CropScience LP and Nichino America, Inc.,	)	FIFRA-HQ-2016-0001
	)	
	)	
Petitioners.	)	

DECLARATION OF CHARLOTTE SANSON
IN SUPPORT OF MOTION FOR ACCELERATED DECISION

I, Charlotte Sanson, hereby declare as follows:

I. PROFESSIONAL BACKGROUND

1. I currently serve as the Bayer CropScience LP ("Bayer") Director of Registrations. In this capacity I manage a team responsible for all of Bayer's federal and state registrations of crop protection pesticide products, including all products that contain the active ingredient flubendiamide.

2. I have worked in the chemicals and pesticides industries since 1986 in technical, marketing, and regulatory positions.

3. I joined Bayer from BASF Corporation ("BASF") in 2014. At BASF I was responsible for state or federal pesticide registrations from 1989 to 2014.

4. I earned a Bachelor of Science in Medical Technology from the University of Dayton in 1981 and a Master of Science in Occupational and Environmental Health from Wayne State University in 1989.

5. I served as the CropLife America Registration Committee Vice Chair from 2013 to 2014. CropLife America is the leading trade association in the United States for crop protection pesticide registrants and distributors. The Registration Committee is comprised of

regulatory affairs professionals of the member companies and regularly meets with EPA to discuss matters of general importance to EPA and the regulated community.

6. I have served in the North America Free Trade Agreement ("NAFTA") Industry Working Group continuously since 2004. This is a group formed by CropLife America to comment on implementation of regulatory processes for NAFTA countries from industry's perspective and to meet with national governments and other stakeholders to discuss matters of general importance to the governments and industry in implementing NAFTA.

7. I have participated in nearly all the recent discussions with the United States Environmental Protection Agency ("EPA") that give rise to this proceeding. As part of my responsibilities in general and for those discussions, I familiarized myself with the regulatory history of flubendiamide.

II. REGULATORY HISTORY OF FLUBENDIAMIDE

A. Conditional Registration of Flubendiamide

8. EPA registered flubendiamide in 2008 under FIFRA § 3(c)(7)(C) (conditional registration of a new active ingredient), applying FIFRA's risk-benefit Registration Standard.

9. EPA's conditional registration included requirements to generate additional data, as set forth in EPA's July 31, 2008 preliminary acceptance letter. Exhibit 8 at 1, 3.

10. At the time of the first approval in 2008, EPA made an affirmative determination, as required under FIFRA, that registration of flubendiamide was in the public interest. Exhibit 21 at 1, 5 (BEAD Public Interest Finding For Flubendiamide (Apr. 15, 2008)). It granted FIFRA registration for five years to allow the registrants to generate and submit additional data to address potential persistence, consistent with FIFRA § 3(c)(7)(C). Exhibit 8 at 1 (July 31, 2008 Preliminary Acceptance Letter), Exhibit 7 at 2 (Aug. 1, 2008 Notices of Registration referring to July 31, 2008 letter).

11. At the same time, EPA established "permanent tolerances" (the limit of residues allowed on food or food crops) for flubendiamide under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301-399) ("FFDCA"). Over the years, numerous additional permanent tolerances have been established through rulemakings under the FFDCA as new crops have been registered and added to the flubendiamide labels. The tolerance-setting process is primarily focused on human health impacts through the diet. Given flubendiamide's very favorable human health profile, EPA has not proposed any changes to flubendiamide's tolerances and none is warranted. However, EPA must take flubendiamide's very favorable human health profile into account in evaluating whether flubendiamide meets FIFRA's risk-benefit standard for registration.

12. Flubendiamide has an excellent safety profile. EPA has concluded that flubendiamide poses no risk of concern to humans (either through diet or worker exposure), fish, mammals, crustaceans, mollusks, beneficial insects, and plants. *See, e.g.*, Exhibit 9 at 2-8 (EPA Flubendiamide Pesticide Fact Sheet (Aug. 1, 2008)). The only potential risk of concern identified by EPA was that flubendiamide and its degradate des-iodo may persist and accumulate over time in farm ponds surrounded by treated fields, potentially to a level that may impact freshwater benthic (bottom dwelling) invertebrates. *Id.* at 8-9. EPA issued the flubendiamide registrations while requiring the registrants to develop data to better understand this potential. *Id.* at 10.

13. EPA's July 31, 2008 letter included a schedule for the registrants to submit proposed protocols for the required data, so that EPA could review the study designs and plans and request modifications as appropriate. Exhibit 8 at 1. EPA also committed to review the data generated and submitted by the registrants, and to engage in discussion with the registrants about

the data and EPA's conclusions. *Id.* at 3. The letter outlined three potential outcomes, including: (a) unconditional registration; (b) EPA and the registrants agreeing on a path forward, revising or providing additional data under a conditional registration; or (c) EPA accepting voluntary cancellation of the flubendiamide registrations. *Id.*

14. EPA stated in the July 31, 2008 letter: "No cancellation shall occur if EPA determines, after review of the data, that the flubendiamide technical product registration could meet the standards for registration set forth in section 3(c)(5) of FIFRA" and Bayer and Nichino agree "to comply with any conditions (including, but not limited to, revised label language, use deletions or conditions of registration) that EPA finds necessary in order to make the registration determination." Exhibit 8 at 3.

15. EPA refused to issue the registrations unless the applicants "concur[red]" that if in the future EPA made an affirmative finding that "further registration of the flubendiamide . . . products will result in unreasonable adverse effects on the environment," the companies would request "voluntary" cancellation of the registrations. *Id.* EPA threatened that, absent this provision, it would not grant the registrations. *Id.* EPA threatened to deny issuance of registrations EPA had already determined were in the public interest absent this purported "condition of registration." *Id.* at 4. EPA's insistence on this Hobson's choice approach is reflected in the July 31, 2008 letter.

B. Data Submission, Evaluation, and Registration Extensions

16. Consistent with the July 31, 2008 letter, the registrants generated the required data. EPA and Bayer communicated about study protocols, study conduct, study reports, and interpretation of the study results. Over time, EPA approved expansion of flubendiamide's registrations to over 200 crops.

17. EPA repeatedly extended the original September 1, 2013 "expiration" date, including an initial extension of the deadline for an additional two years to allow for further data generation and review, and a flurry of more recent extensions until the issuance of its January 29, 2016 Decision Memorandum and demand for voluntary cancellation.

18. EPA commonly uses its authority to request additional data to refine its risk assessments and to identify risk mitigation consistent with FIFRA. EPA often communicates with registrants to evaluate potential mitigation options and implement them. Sometimes this is done while data are being generated that may allow the mitigation to be refined, removed, or a substitution for such measures made in the future. In light of flubendiamide's favorable human health and non-target organisms safety profile and its value to agriculture, and the substantial amount of scientific data supporting its registration, it is consistent with EPA's fulfillment of its responsibilities under FIFRA that right up until the end of 2015 EPA repeatedly expressed its intention to adopt further risk mitigation measures and extend the registrations to allow the generation of additional data.

19. During its ongoing review and discussion of the submitted data and continued monitoring, EPA repeatedly confirmed that the registrants have satisfied the conditional registration requirements and agreed to extend the registrations. In a July 18, 2013 letter extending the registrations to August 31, 2015, EPA confirmed that "[a] s of July 31, 2012, [the registrants] . . . ha[ve] submitted all data required by the original conditions of registration for flubendiamide." Exhibit 10 (July 18, 2013 EPA Letter re Extension of Flubendiamide Registrations to Aug. 31, 2015). On August 26, 2015, EPA again extended the registrations to December 10, 2015 to "provide time for [the registrants] and the EPA to discuss whether potential additional data requirements and label amendments are necessary to address areas of

uncertainty" and again confirmed that "[a]s of July 31, 2012, [the registrants] ha[ve] submitted all data required by the original conditions of registration for flubendiamide." Exhibit 12 (Aug. 26, 2015 EPA Letter re Extension of Flubendiamide Registrations to Dec. 10, 2015).

20. In discussions with the registrants in July and August 2015, EPA presented a plan for continuing the registrations for all crop uses that involved reducing exposure by eliminating aerial applications, limiting use to a single application per growing season for all crops, and conducting additional studies. Exhibit 11 at 2 (Aug. 4, 2015 email from C. Rodia to N. Delaney). EPA provided a specific list of proposed additional studies, including an expanded stream and pond monitoring program and toxicity studies on additional aquatic species. *Id.* EPA proposed a three-year extension of the registrations to allow the data to be generated and reviewed. *Id.* EPA and the registrants reached an agreement regarding what studies would be performed and work was underway to develop and deliver for EPA's review protocols and scoping documents for the studies.

21. EPA and the registrants continued to have discussions into December 2015. Bayer offered to eliminate certain uses and to work with EPA to refine limitations on use rates and applications for remaining uses to reduce exposure while meeting commercial needs. Bayer also agreed to conduct additional studies, including the additional ecotoxicity studies and the expansion and continuation of the monitoring program, which was anticipated to cost millions of dollars. EPA indicated that it planned to extend the registrations for three years while the registrants generated the additional data.

22. On December 1, 2015, Bayer and Nichino met with EPA to discuss the path forward and to reiterate the registrants' commitment to generate the additional scientific data EPA had identified.

23. The registrants also provided a comparative assessment with a competitive pesticide, methoxyfenozide, that has nearly the same persistence and risk profile to benthic aquatic invertebrates as flubendiamide. EPA required similar water monitoring studies for that compound, resulting in levels of detection that, like flubendiamide, were below levels of concern at all of the monitoring sites tested.

24. For methoxyfenozide, EPA chose to rely on the actual monitoring data showing no levels of concern rather than its modeling which predicted much higher exposures that exceeded levels of concern. EPA's risk assessment for methoxyfenozide explained that the modeling results "likely overestimate concentrations in streams and various other kinds of water bodies" for a number of reasons, including "washout, dispersion, burial of sediment and other dissipative processes that aren't simulated." Exhibit 49 at 21 (Preliminary Environmental Fate and Ecological Risk Assessment for Methoxyfenozide (Sept. 16, 2015)). EPA also determined that methoxyfenozide concentrations in flowing water bodies are not expected "to accumulate at such a high concentration[] from year to year because of downstream advective removal." *Id.*

25. For methoxyfenozide, EPA properly focused on the higher-tier, actual monitoring data rather than overly conservative modeling, and has not taken steps to cancel the methoxyfenozide registrations. Singling out flubendiamide for different, extreme treatment is not consistent with FIFRA nor is it fair in light of how EPA is approaching its overall risk-benefit regulation of pesticides.

26. Up until early December 2015, EPA was consistent in discussing with the registrants EPA's plan to extend the flubendiamide registrations for three years until 2018 and to require additional data. EPA and the registrants also discussed potential mitigation. The registrants proposed mitigation through changes to the product label and conducted calculations

to confirm that the mitigated label would pass EPA's risk assessment, even using a methodology the registrants believe to be more conservative than required.

27. On December 8, 2015, EPA extended the December 10 expiration date to December 18, 2015 "to provide additional time for BCS [Bayer CropScience] and EPA to discuss areas of uncertainties." Exhibit 13 (Dec. 8, 2015 EPA Letter re Extension of Flubendiamide Registrations to Dec. 18, 2015). At a high level meeting on December 15, 2015 involving the Assistant Administrator of EPA responsible for all pesticides and the CEOs of both Bayer and Nichino, the Assistant Administrator described his view of flubendiamide, repeatedly using precautionary language and contending that flubendiamide should be cancelled based on its persistence alone, even though no harm had been identified, to eliminate any possibility of future harm. This is contrary to the risk-benefit approach required by FIFRA. The Assistant Administrator contended that, absent any action by EPA beforehand, the registrations would expire on December 18, 2015 and indicated that EPA would consider whether to take action and would inform the registrants of its decision by the end of the day on December 18, 2015.

28. The registrants raised the practical difficulties of that timing and requested that EPA extend the December 18, 2015 date to help ensure an orderly process and that EPA advise the registrants promptly when a decision had been made. EPA committed to respond on the extension and suggested that the registrants submit the best, final mitigation proposal they could develop, as promptly as possible, in light of an internal briefing of the EPA Assistant Administrator the following day. The registrants quickly convened their experts and prepared and submitted a further mitigation proposal later the same day.

C. Change in EPA's Toxicity Endpoint

29. Up to this point, the open scientific question concerned whether the modeling and monitoring data suggested that flubendiamide or the des-iodo metabolite might accumulate to a

level of concern based on the toxicity data. These data include a 2010 spiked sediment study Bayer conducted specifically to focus on the area of EPA's concern: the level of toxicity to benthic aquatic invertebrates in pore water and sediment. As EPA confirmed in its May 21, 2008 review of a spiked water study submitted in 2004, the Agency prefers the spiked sediment methodology for this purpose. Exhibit 33 at 2 (Des-iodo Spiked Water Study Data Evaluation Record (May 21, 2008)).

30. In a spiked sediment study, the test compound is introduced into the sediment and the system is allowed to equilibrate. In a spiked water study, the chemical is introduced directly into the overlying water.

31. On December 16, 2015, EPA's Environmental Fate and Effects Division ("EFED") briefed the EPA Assistant Administrator as planned. In a new development, after years of discussion, the high level meeting the day before, and visibility of the registrants' submission of a "final" mitigation plan that passed even EFED's conservative, theoretical modeling approach, EFED stopped using the directly relevant toxicity endpoint from the des-iodo spiked sediment study that had been the basis of the many discussions, technical evaluations, and mitigation plans of the preceding months. It based the briefing on a different endpoint that appeared to be designed to ensure, after the fact, that the registrants' "final" mitigation proposal would not be sufficient.

32. The spiked sediment study specifically conducted to assess the potential toxicity of des-iodo to benthic aquatic invertebrates in pore water in sediment showed no observable adverse effects at any of the levels tested, supporting a level of concern for des-iodo of 19.5 parts per billion ("ppb") (as calculated by EPA using a time-weighted average approach) or 22 ppb (as calculated in the report based on measured concentrations). Although this is the most

appropriate study to measure toxicity from the potential toxicity route of exposure, EPA chose at the eleventh hour to ignore this study and revert to an endpoint derived from the less appropriate, earlier-conducted spiked water study, leading to a toxicity endpoint of 0.28 ppb, 70 times lower than the more environmentally relevant data conducted using EPA's preferred methodology support. This reversion ensured that EPA could continue to "predict" exceedances of levels of concern even after making overdue and necessary corrections to its theoretical modeling.

D. EPA's Cancellation Determination and Notice of Intent to Cancel

33. This dramatic change in the ground rules for an apparently preordained result was shocking to the registrants. Bayer wrote to the Assistant Administrator on December 16 to seek to confirm whether he was aware of this sudden change in approach and lack of transparency, and to request the underlying science. Exhibit 14 (Dec. 16, 2015 Bayer CropScience LP Email re Change in Flubendiamide Ecotoxicity Endpoint).

34. On December 18, 2015, EPA provided a letter "extending the expiration date of December 18, 2015 to January 15, 2016." Exhibit 15 at 1. EPA also scheduled a meeting with the registrants for January 6, 2016 at which EPA EFED would present its evaluations.

35. The registrants reviewed the information provided by EPA over the holidays and also submitted two formal reports on environmental fate and ecotoxicology data whose conclusions had previously been previewed with EPA. In particular, one of the studies showed that des-iodo, the flubendiamide metabolite whose potential toxicity forms the basis for EPA's proposed cancellation, degrades when exposed to sunlight. Bayer submitted both study reports to EPA on January 5, 2016.

36. At the January 6 meeting, EPA presented its scientific position, relying on the lower toxicity endpoint and theoretical modeling to support its position that flubendiamide is accumulating or will accumulate in vulnerable water bodies above a level of concern. EPA

acknowledged that things were "very dynamic" and the timing of its change was "unfortunate." It sought to explain what activities had taken place within the Agency at the end of the year that had not been visible to the registrants.

37. The registrants asked EPA to confirm, if EPA decided the flubendiamide registrations should not continue beyond the January 15, 2016 date, whether the Agency: (1) would pursue "automatic" expiration without further action; (2) would seek to implement the unlawful forced "voluntary" cancellation condition; or (3) would issue a proper notice of intent to cancel and follow the cancellation proceedings required by FIFRA § 6(b). EPA ultimately confirmed that it would demand "voluntary" cancellation and seek cancellation under FIFRA § 6(e) if Bayer and Nichino refused to request "voluntary" cancellation. On January 14, 2016, EPA again extended the conditional registration for flubendiamide, this time to January 29, 2016. Exhibit 16.

38. On January 29, 2016, EPA issued a letter, formally notifying Bayer and Nichino that it determined flubendiamide poses unreasonable adverse effects to the environment and requesting that Bayer and Nichino "voluntarily" cancel their registrations for flubendiamide within one week of the letter. Exhibit 17 at 2. EPA further stated that the failure to submit the requested voluntary cancellation would cause EPA to initiate a cancellation proceeding consistent with FIFRA § 6(e). *Id.*

39. On February 5, 2016, Bayer and Nichino responded to EPA's request. The response stated: (1) that the "voluntary" cancellation condition was an unlawful condition of registration; (2) that if EPA determined flubendiamide poses unreasonable adverse effects to the environment, the proper procedure is to issue a Notice of Intent to Cancel pursuant to FIFRA

§ 6(b); and (3) that the available evidence shows that flubendiamide does not pose unreasonable adverse effects to the environment. Exhibit 18 at 1-2.

40. On March 1, 2016, EPA provided its Notice of Intent to Cancel the flubendiamide registrations to Bayer and Nichino. The NOIC was dated February 29, 2016, and was published in the Federal Register on March 4, 2016. Exhibit 20 (81 Fed. Reg. 11,558 (Mar. 4, 2016)).

41. Also on March 1, 2016, EPA issued press releases and posted information on its website announcing that EPA was seeking cancellation because flubendiamide products "pose a risk to aquatic invertebrates that are important to the health of aquatic environments."[1] EPA asserted that "[r]equired studies showed flubendiamide breaks down into a more highly toxic material that is harmful to species that are [an] important part of aquatic food chains, especially for fish, and is persistent in the environment." EPA "concluded that continued use of the product would result in unreasonable adverse effects on the environment." EPA posted the NOIC and 11 other documents totaling 504 pages regarding the merits of its cancellation decision.[2]

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 11th day of April, 2016

Charlotte Sanson

Charlotte Sanson

[1] EPA Moves to Cancel the Insecticide Flubendiamide (Mar. 1, 2016) (Exhibit 19).

[2] Flubendiamide – Notice of Intent to Cancel and Other Supporting Documents, https://www.epa.gov/ingredients-used-pesticide-products/flubendiamide-notice-intent-cancel-and-other-supporting (last visited Mar. 31, 2016).

EXHIBIT 3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of:	)	
	)	
Bayer CropScience LP and Nichino America, Inc.,	)	FIFRA-HQ-2016-0001
	)	
Petitioners.	)	

DECLARATION OF LYDIA COX
IN SUPPORT OF MOTION FOR ACCELERATED DECISION

I, Lydia Cox, hereby declare as follows:

I. PROFESSIONAL BACKGROUND

1. I have been employed by Nichino America, Inc. since 2013 as the Director of Regulatory Affairs. In this role I manage a small group of regulatory managers and a regulatory specialist who have responsibility for obtaining and maintaining registrations for pesticides in the United States and Canada.

2. Prior to 2013 I was employed by DuPont – Haskell Global Centers for Health and Environmental Sciences as a Toxicology Business Liaison to the Chemicals and Fluoroproducts business unit. Previous positions include Senior Toxicologist at Critical Path Services, a consulting firm, and Senior Research Toxicologist at DuPont – Haskell Laboratory where I was a study director, study monitor, and technical group leader. With the exception of one year during which I focused on the industrial chemical sector, my previous employment over the course of more than thirteen years has been solely or largely focused on development and registration of pesticides.

3. I have a BS in Animal Science from Cornell University and a PhD in Toxicology from University of the Sciences. I was a post-doctoral fellow and research associate in Environmental Medicine at New York University Medical Center prior to joining DuPont. I am a Diplomate of the American Board of Toxicology (1993-1999 and 2011-present). Since 2013, I have become Nichino's point of contact for various Crop Life America committees and attended CLA's annual regulatory conference.

II. DEVELOPMENT OF FLUBENDIAMIDE

4. Nichino America, Inc. ("Nichino") is a wholly owned subsidiary of Nihon Nohyaku Co., Ltd. ("NNC"). NNC was established in 1928 and is a basic researcher and manufacturer of plant protection products based in Tokyo, Japan. NNC's mission is to meet current needs in global crop protection markets by introducing innovative agrochemicals that can contribute to healthy food production while protecting the environment. NNC has conducted insecticide discovery research at its Research Center near Osaka, Japan since 1990.

5. Flubendiamide was invented by NNC. In the course of this research, in 1993 it discovered a lead compound for a new insecticide from the class of phthalic acid diamides. It synthesized two thousand derivatives from this initial discovery and conducted many studies to improve activity before it finally discovered flubendiamide in 1998. NNC and Nichino have spent more than $65 million on the initial discovery, data, and development costs to obtain the US registrations and to bring flubendiamide to the US market.

6. NNC entered into a licensing, product development, and marketing agreement with Bayer CropScience LP, under which Bayer serves as Nichino's regulatory agent for flubendiamide and sells flubendiamide products under the Belt® brand name. Nichino sells flubendiamide products under the Vetica® and Tourismo® brand names.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 8th day of April, 2016

Lydia Cox

Lydia Cox

EXHIBIT 4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of:	)	
	)	
Bayer CropScience LP and Nichino America, Inc.,	)	FIFRA-HQ-2016-0001
	)	
	)	
Petitioners.	)	

EXPERT DECLARATION OF DAVID AMES HERBERT JR., PH.D.
IN SUPPORT OF MOTION FOR ACCELERATED DECISION

I, David Ames Herbert Jr., hereby declare as follows:

I. BACKGROUND AND EXPERIENCE

1. I am a professor of entomology in the Virginia Tech Department of Entomology and have been located at the Tidewater Agricultural Research and Extension Center (TAREC) since 1988. I hold a Bachelor's of Science degree in Biology from Johnson State College, and Masters of Science and Doctor of Philosophy degrees in entomology from Auburn University.

2. The focus of my work at TAREC is to develop (25 percent Research appointment) and implement (75 percent Extension appointment) programs to improve management of insect pests of soybean, peanut, cotton and small grains that reduce reliance on pesticides while maintaining crop quality and profitability. I have state-wide responsibility for the insect pests of these crops, including 600,000 acres of soybean, 18,000 acres of peanut, 90,000 acres of cotton, and 350,000 acres of small grains grown by Virginia farmers annually. My research focuses on the development of better pest control practices (Integrated Pest Management or "IPM") to improve productivity while protecting the environment, and includes the conduct of field studies comparing the efficacy of different insecticides in controlling various insect pests on the aforementioned crops. My Extension work includes meeting and engaging directly with growers across the state to learn about the problems growers are facing in the field and to promote improved grower practices based upon our research findings.

3. I have conducted over 100 pesticide field studies and authored over 65 papers in scientific journals and over 130 Extension publications. I provide insect pest[1] and insecticide control recommendations to growers in several annually updated crop production guides, including the Virginia Cooperative Extension's annual Pest Management Guide for Field Crops,[2] the Virginia Cotton Production Guide[3] and Virginia Peanut Production Guide.[4]

4. I have served as the Commonwealth of Virginia's Integrated Pest Management Coordinator since 1997. My responsibilities in this position include: (1) to lead the development of the USDA-NIFA grant that funds the IPM program in the Virginia Tech College of Agriculture and Life Sciences, and (2) to coordinate the activities of participating weed scientists, plant pathologists, and entomologists in their efforts to reduce pesticide use while fostering improved conditions in schools and public housing, agricultural crops, recreational lands, plant nurseries, and homegrounds.

5. I have received recognition for my work in furtherance of IPM practices, including the Insects Research and Control Conference Recognition Award for Excellence in Cotton Integrated Pest Management, which I received this year, and a Lifetime Achievement Award, which I received from the Friends of Southern IPM in 2012.

6. Exhibit 37 is a copy of my curriculum vitae further detailing my qualifications, experience, publications and presentations.

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[1] *See, e.g.*, D. Ames Herbert, Jr., and Sean Malone, Mid-Atlantic Guide to the Insect Pests and Beneficials of Corn, Soybean and Small Grains (Virginia Integrated Pest Management, Virginia Coop. Extension Publ'n 444-360, 2d ed. 2011) (Exhibit 38).

[2] D. Ames Herbert, Jr., and Michael Flessner, Pest Management Guide Field Crops 2016 (Excerpt, Chapters 1 & 4) (Virginia Coop. Extension Publ'n 456-016, 2016) (Exhibit 42).

[3] W. Hunter Frame, D. Ames Herbert, Hillary Mehl, et al, Virginia Cotton Production Guide 2016 (Virginia Coop. Extension Publ'n AREC-124NP, 2016) http://www.pubs.ext.vt.edu/AREC/AREC-124/AREC-124.html.

[4] Maria Balota, D. Ames Herbert, et al, Virginia Peanut Production Guide 2016 (Virginia Coop. Extension Publ'n AREC-157, 2016), http://pubs.ext.vt.edu/AREC/AREC-157/AREC-157.html (follow PDF hyperlink for complete copy).

II. INTRODUCTION TO IPM AND IRM

7. **Background on Integrated Pest Management ("IPM")**: IPM is the implementation of diverse methods of control (e.g., using pest resistant varieties, altering planting times to escape periods of greatest pest pressure, conserving beneficial species, and using insecticides only when pest populations overwhelm these other management efforts), paired with scheduled pest monitoring to efficiently manage pests while reducing unnecessary pesticide applications.[5] The IPM paradigm has been promoted and practiced in U.S. agriculture since the mid-1970s.

8. Each year entomologists at universities across the U.S publish IPM recommendations that address the crops and insect pests local to their state. These publications identify and recommend particular insecticides for use to control identified crop pests for each crop. I help coordinate the content for these publications for Virginia. I am also familiar with the IPM publications of other universities.

9. Conserving beneficial species, also termed 'natural enemies', is a cornerstone of IPM programs. Crop fields are the equivalent of small, temporary agroecosystems that, when left alone, generate thousands of natural enemies—predators, spiders, parasites—that can feed on pest species and in many cases prevent them from ever reaching levels that require insecticide application. Previous research studies have shown that a rich and diverse natural enemy community can be critical for suppressing pest populations and reducing the number of insecticide applications that growers have to use. Conversely, research also shows that broad-spectrum insecticides can destroy natural enemies resulting in reduced pest control, and flaring of secondary pests that may require additional insecticide sprays. This is why the use of broad-spectrum insecticides is generally discouraged when a narrow spectrum or more specific

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[5] *See* Integrated Pest Management Program (IPM), USDA National Institute of Food and Agriculture, https://nifa.usda.gov/program/integrated-pest-management-program-ipm (last visited Apr. 6, 2016).

insecticide will control the target pest. For the reasons above, I encourage growers to use insecticides that are consistent with IPM whenever feasible to do so.

10. **Background on Mode of Action ("MOA")**: An insecticide's MOA is the mechanism by which it kills the species it is intended to target. Insecticides are divided into different classes, each with a different MOA.

11. **Background on Insect Resistance Management ("IRM")**: Insect pests are known to develop resistance to insecticides, especially if there is an over reliance and over use of insecticides with the same MOA. A standard recommended practice for preventing or slowing resistance development is to rotate insecticides with different MOAs, especially if multiple applications are used during the growing season.[6]

12. When IRM is not practiced, resistance may develop. For example, until relatively recently, growers across the U.S. have relied heavily on insecticides in the pyrethroid class to control *Helicoverpa zea*, a caterpillar pest that attacks a wide variety of agricultural crops. The accepted common name of this pest is Corn earworm (so named because the worm is found in the tips of sweet corn ears), but it is also known by other names depending on the crop that it is attacking (e.g., Cotton bollworm for its destruction of cotton bolls, Tomato fruitworm for boring into tomatoes and peppers, and Soybean podworm for its destruction of soybean pods and seed[7]). This repeated use of pyrethroids over many years has resulted in Corn earworm populations

[6] 2016 Insect Control Guide For Agronomic Crops (Mississippi State University Extension Publ'n 2471, 2016) (Exhibit 39 at 5) ("With foliar insecticides, you can delay resistance by not exposing successive generations of pests to insecticides from the same class. Rotating different classes of insecticides against different generations of pests is an effective resistance management tool because insects resistant to one class of chemistry are often susceptible to insecticides from a different class.")

[7] Dominic Reisig and D. Ames Herbert Jr., Soybean Insect Guide (NC State University, Virginia Coop. Extension 2013), http://unitedsoybean.org/wp-content/uploads/47574_Insect-Guide1.pdf

developing resistance to those products. I have encountered and written about the development of Corn earworm resistance to pyrethroids in the past.[8]

13. My laboratory at the TAREC has been monitoring the susceptibility of Corn earworm to pyrethroid insecticides since 2003. We have seen a gradual increase in resistance so that in the last few years, more than 30% of individual insects tested are now surviving exposure. As a result, growers are experiencing control failures and in some cases, requiring retreatment of problem fields.

III. FLUBENDIAMIDE AND ITS BENEFITS

14. **Background on Flubendiamide:** Flubendiamide, under the trade name of Belt®, was designed to target Lepidopteran larval, or caterpillar, pests of agricultural crops. The specificity of its mode-of-action—that it kills only caterpillars—makes Belt® unique among insecticides. This attribute is a fundamental difference from all other agricultural insecticides and confers several advantages specific to the control of lepidopteran pests that are addressed below.

15. **Flubendiamide's Mode of Action:** Belt® is in a relatively new and unique class of insecticides-- the diamides -- that was designed to target caterpillar pests. There are only two other insecticides in this class, chlorantraniliprole and cyantraniliprole,[9] and those products target a broader list of species—an important distinction that is addressed below.

16. **Flubendiamide's Efficacy:** Belt®'s narrow function is to provide control of caterpillar pests. Numerous field research trials over recent years by entomologists at major universities across the U.S.[10] have consistently shown that timely foliar applications of Belt®

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[8] *See, e.g.*, Ames Herbert, Virginia Soybeans: Pyrethroid Resistance Hits High Levels, So Understand Treatment Options (AgFax Aug. 20, 2012) (Exhibit 40).

[9] *See* Insecticide Resistance Action Committee, Mode of Action (Dec. 7, 2015), http://www.irac-online.org/mode-of-action/ (follow Classification Scheme hyperlink, page 10, Diamides).

[10] Bayer Flubendiamide Benefits Document (May 20, 2015) at Appendix B, 110-226. (Exhibit 22).

provide excellent levels of control that usually exceed the results of predecessor compounds (pyrethroids, organophosphates) for a great variety of caterpillar pests, and across many crops. A number of these same field research trials, including 10 that I conducted, were included in Bayer's benefits submissions to EPA. Exhibit 22 at Appendix B, 145-146, 152-155, 170-171, 179-180, 183, 186, 189.

17. One example of a pest that Belt® controls is the Corn earworm, which is one of the most destructive caterpillar pests in the southeast and mid-southeastern U.S. This pest requires constant surveillance by growers, and in many cases necessitates the use of insecticides when populations exceed the economic threshold (when the value of the potential crop loss exceeds the cost of control).

18. In field trials that I conducted in Virginia as well as in the fields of local growers with which I am familiar, Belt® consistently controls Corn earworm infestations in cotton, peanuts, and soybeans (i.e., it eliminates the large majority of the caterpillar pests in a crop after application and continues to protect the crop through its residual activity).[11] Belt's efficacy in controlling Corn earworm and Soybean looper is also reflected in the data submitted to EPA by Angus Catchot, an Extension Entomologist at Mississippi State University, and which is included in Bayer's Benefits Document Supporting the Continued Registration of Flubendiamide (Belt® SC).

19. **Flubendiamide's Non-systemic Activity:** Belt® is not a systemic insecticide. That is, it is not taken up by the plant via the foliage and / or roots and is not incorporated into the above-ground plant parts. Systemic insecticides, once taken up by the plant, can expose pests to the active ingredient of the product for much longer period of time compared to non-systemic foliar-applied insecticides. Prolonged pest exposure to systemic insecticides, particularly at sub-lethal dosages, which can expose multiple generations of the pests, has resulted in the

[11] *See, e.g.*, K. L. Kamminga, D.A. Herbert, Jr. & S. Malone, Evaluation of Selected Foliar Applied Insecticides for Control of Corn Earworm in Virginia Soybean (Virginia Tech Tidewater Agric. Res. & Ext. Ctr. 2007) (Exhibit 22 at 155).

development of resistance by some insects to certain products. Because Belt® is non-systemic, target pests are only exposed during specific windows of time (up to three weeks), greatly reducing the possibility of resistance development. Having a shorter window of activity also allows growers to rotate products with different MOAs, which is a recommended practice for preventing resistance development. When Belt® became available, we started recommending it to our growers as a non-pyrethroid option. Chlorantraniliprole, one of the only IPM alternatives identified in the EPA BEAD Review of Bayer CropScience LP Flubendiamide Benefits Document ("BEAD Analysis"), *is* a systemic insecticide, and its use could therefore have greater potential to result in the development of pest resistance.

20. **Residual Activity:** Although not systemic, Belt® does have longer residual activity than pyrethroids if applied correctly and in the absence of excessive rainfall. Belt® is applied as a foliar spray and once dried on the leaf surface, field trials have shown that caterpillars feeding on treated leaf surfaces are killed for up to three weeks after application. This is not the case with most other non-systemic insecticides, which only remain active for hours or days. Belt®'s longer residual activity offers a huge advantage to growers because it requires fewer applications. The fewer the applications of a pesticide that are required, the less active ingredient that is released into the environment.

21. If applied at the right time in the pest cycle, e.g., when pests are first encountered, a single application of Belt® can provide season-long control. This is in contrast to short-lived products (pyrethroids) that may require one or more re-treatments to achieve equal levels of control. For example, there have been seasons in Virginia, when the Corn earworm infestations in soybean crops were so severe that they have required repeated applications of pyrethroids, because of their short residual activity.

22. **Low Toxicity to Natural Enemies:** As mentioned above, Belt® was designed to provide specific activity against caterpillar pests. Research (including an ongoing Ph.D. student project under my supervision) has found that Belt® has virtually no negative impact on natural enemy populations. In a 2-year study in southeast Virginia soybean fields, the student found an

astounding number of natural enemy species—111 different species—including many spider species never previously reported. Applications of Belt® had no negative impact on these populations, compared with a pyrethroid insecticide that severely reduced natural populations during the time when they would be present to feed on pest species. These findings are important because when natural enemy species are conserved, they can help control crop pest populations. These findings are also consistent with the findings of numerous other entomologists,[12] the IR-4 Project, [13] and EPA's own BEAD analysis,[14] all of which speak to Belt's low toxicity to beneficial insects.

23. **Low Toxicity to Pollinators:** Belt® is also essentially non-toxic to honey bees and other pollinators. This is an increasingly important attribute for an insecticide to have, given growing concerns about the health of honey bee populations in the U.S. – concerns that EPA[15] and USDA[16] have raised. Growers have a great incentive to use practices and pesticides that protect their crop from pests, while protecting pollinators. Indeed, many growers rely on honey bees to pollinate their crops[17] and pay honey bee producers to place hives near their fields during critical pollination periods. Based on my experience collaborating with growers in Virginia, the last thing a grower wants is to the kill honey bees that were introduced in order to enhance crop

[12] Dr. J. Greene, Professor Of Entomology, Clemson University and E. Natwick, Farm Advisor Entomology, University of California ANR Cooperative Extension, Letters Re Support Of Flubendiamide, Bayer Flubendiamide Benefits Document (May 20, 2015) (Exhibit 22 at 244-245, 253-254).

[13] Letter from J. Baron (IR-4) To J. Housenger (EPA) Re Comments On Flubendiamide Notice Of Intent To Cancel (Mar. 28, 2016) (Exhibit 26).

[14] EPA BEAD Review of Bayer Flubendiamide Benefits Document (July 24, 2015) (Exhibit 23).

[15] *See, e.g.*, EPA, EPA Takes Strong Steps to Better Protect Bees from Pesticides (May 28, 2015), https://www.epa.gov/pesticides/epa-takes-strong-steps-better-protect-bees-pesticides.

[16] United States Department of Agriculture, Preventing or Mitigating Potential Negative Impacts of Pesticides on Pollinators Using Integrated Pest Management and Other Conservation Practices, Agronomy Technical Note No. 9 (Feb. 2014) (Exhibit 41).

[17] D. Ames Herbert, Jr., and Michael Flessner, Pest Management Guide Field Crops 2016 (Virginia Coop. Extension Publ'n 456-016, 2016) (Exhibit 42) at 1-45.

yields. Belt® is that rare bee-safe product with no restrictions on the label pertaining to pollinators. Many of the alternatives to Belt® identified by EPA in the BEAD Analysis, including pyrethroids, are toxic to pollinators and have restrictions on their use as a result.

24. Peanuts are an important crop for the Virginia agricultural economy. In 2010, I conducted a Heliothine (caterpillar) complex study, which showed Belt® to be the most efficacious insecticide for protecting peanuts crops from these pests. Belt® was found to have nearly 90 percent efficacy, out-performing similar compounds and products from other classes of peanut insecticides. In an earlier study evaluating selected foliar treatments for control of the beet armyworm pest on peanuts, Belt® was also found to be among the most efficacious treatments.[18] Belt® is also a preferred insecticide for peanuts because it is non-toxic to the insects that pollinate flowering peanut plants.

IV. CONCLUSION

25. **Overall Excellent Profile:** Belt® is a product that fits perfectly with IPM programs, provides excellent control of Lepidopteran pests while conserving natural enemies, and is non-toxic to pollinators—a 'smart bomb' that targets caterpillar pests with no collateral damage to important natural enemies or pollinators. For these reasons, I recommend use of Belt® for the control of a variety of caterpillar pests in my annual pest and insecticide control recommendations.[19]

26. In its July 24, 2015 review of flubendiamide benefits information, EPA's Biological and Economic Analysis Division (BEAD) largely acknowledged the benefits of flubendiamide but underestimated the overall value of growers having access to the product. For example, BEAD agreed that pyrethroids "are the likely alternatives to flubendiamide in alfalfa,

[18] D.A. Herbert, Jr. & S. Malone, Evaluation of Selected Foliar Applied Insecticides for Control of Beet Armyworm in Virginia Peanut" (2007), Bayer Flubendiamide Benefits Document (May 20, 2015) (Exhibit 22 at 152).

[19] *See* D. Ames Herbert, Jr., and Michael Flessner, Pest Management Guide Field Crops 2016 (Virginia Coop. Extension Publ'n 456-016, 2016) (Exhibit 42).

peanuts, and soybeans" but contended that because flubendiamide is used on "very few acres" on these crops, there is "consequently little benefit to those growers." Exhibit 22 at 8. The benefits of a product like flubendiamide are better measured not by the total number of acres treated, but by the particular attributes the product provides for growers (e.g. its highly-specific efficacy against caterpillar pests and lack of toxicity to bees and natural enemies of pests.) Flubendiamide provides an important tool for growers to use if and when specific caterpillar pest pressures arise, consistent with IPM. Flubendiamide is likely to play a larger role as IPM practices are adopted more widely, as the importance of pollinator protection increases, and as resistance issues grow. It would therefore be a mistake to deny growers the use of this important pest control tool.

27. **Problems Associated With the Loss of Belt®**: In EPA's Decision Memorandum in support of its Notice of Intent to Cancel Flubendiamide, the Agency asserts that although flubendiamide presents a variety of benefits to growers and the environment, there will still be "alternatives" if EPA cancels all flubendiamide registrations. EPA's Decision Memorandum does not identify those alternatives or explain whether or to what extent they replicate Belt's benefits.

28. Based on my direct knowledge of soybean, peanut, and cotton crops in Virginia, the most common and destructive pest threats to those crops, and historic grower practices, in my opinion the lack of access to Belt® could result in movement of growers back to more broad-spectrum insecticides, reversing important progress made toward grower adoption of IPM management practices. Prior to the advent of Belt®, many growers relied on the use of insecticides in the pyrethroid class for controlling caterpillar pests and would likely resort to those if Belt® was no longer available. EPA acknowledges in the BEAD analysis that many growers are likely to substitute use of pyrethroids for Belt® if it is no longer available. This substitution of pyrethroids presents three problems—one, that resistance to pyrethroids has been confirmed for Corn earworm, Soybean looper, and other caterpillar pests; two, it has been proven that pyrethroids destroy non-target beneficial natural enemy species; and three, pyrethroids are

toxic to pollinators and cannot be applied if crops are flowering and bees are actively foraging. Those growers seeking to continue to practice IPM will have very limited remaining options for control of caterpillar pests and will be less equipped to combat pest resistance if and when it develops.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 8, 2016.

David Ames Herbert Jr.

EXHIBIT 5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of:	)	
	)	
Bayer CropScience LP and Nichino America, Inc.,	)	FIFRA-HQ-2016-0001
	)	
	)	
Petitioners.	)	

EXPERT DECLARATION OF DWAYNE R. J. MOORE, PH.D.
IN SUPPORT OF MOTION FOR ACCELERATED DECISION

TABLE OF CONTENTS

I, Dwayne R. J. Moore, hereby declare as follows:

I. PROFESSIONAL EXPERIENCE

1. I have served as an ecological risk assessor for the past 25 years, the first seven years with Environment Canada (the Canadian analogue to the U.S. Environmental Protection Agency (EPA)), the next seven years as a Senior Associate with The Cadmus Group, and the last 11 years as a Senior Vice President and Senior Scientist with Intrinsik Environmental Sciences. During my career, I have led and conducted numerous refined risk assessments on the effects of industrial chemicals and pesticides to aquatic life and wildlife. I hold a Bachelor's of Science degree in Plant Sciences from the University of Western Ontario, and Masters of Science and Doctor of Philosophy degrees in community ecology from the University of Ottawa.

2. While at Environment Canada, I developed guidance for conducting ecological risk assessments of priority industrial substances, led and participated in priority substance assessments, and developed water quality guidelines for toxic chemicals that ensure protection of aquatic life. For the last 17 years, I have served as a consultant and ecological risk assessor to private firms, non-government organizations, and various government agencies in Canada, the United States, Europe and Australia. The agencies have included Environment Canada, Health Canada, Canadian Nuclear Safety Commission, Canadian Department of Fisheries and Oceans, Provinces of British Columbia and Ontario, Canadian Council of Ministers of the Environment, U.S. Army Corps of Engineers, U.S. Department of Energy, U.S. Environmental Protection Agency, Australian Pesticides and Veterinary Medicines Authority, and Department for Environment in the United Kingdom.

3. I have authored over 50 peer-reviewed publications and 11 book chapters, edited a book, served on numerous Scientific Advisory Panels and Boards for the U.S. government,

been a member of editorial boards for two major journals in the area of ecological risk assessment and toxicology, and helped organize many Society of Environmental Toxicology and Chemistry (SETAC) Pellston workshops on specialized topics in risk assessment.

4. I am an expert in, among other areas, ecological risk assessments for pesticides and industrial chemicals, wildlife exposure modeling, development of water quality guidelines and criteria for protection of aquatic life, community ecology, statistics, uncertainty analysis, and analysis of toxicity data. Since becoming a consultant in 1996, I have developed probabilistic exposure and risk models for birds and mammals exposed to bait, granular, seed treatment and flowable pesticides. I have also led and participated in many refined aquatic and wildlife exposure and risk assessments for pesticides, including insecticides such as aldicarb, azinphos methyl, bifenthrin, brodifacoum, carbofuran, carbosulfan, chlorpyrifos, clothianidin, dimethoate, diphacinone, imidacloprid, malathion, and methyl parathion.

5. For Environment Canada, I led a team that developed the guidance manual for deriving Ideal Performance Standards (IPS, equivalent to environmental quality criteria) for pesticides in Canada. Subsequent to preparation of the guidance manual, my team completed development of IPS for protection of aquatic life for 8 priority pesticides in Canada. Previously, I led the ecological risk assessment for the polychlorinated biphenyl (PCBs)-contaminated Housatonic River in Massachusetts on behalf of EPA. I also co-led the ecological risk assessment of the Calcasieu Estuary in Louisiana, also on behalf of EPA.

6. Exhibit 43 is a copy of my curriculum vitae further detailing my qualifications, experience, publications and presentations.

II. SCOPE OF DECLARATION

7. I was engaged by Bayer CropScience LP (Bayer) to review and evaluate the ecological risk assessments conducted by EPA for benthic invertebrates potentially exposed to

flubendiamide. Specifically, I was asked: 1) to review the studies, data, guidelines, and risk assessments for benthic invertebrates potentially exposed to flubendiamide and the degradation metabolite, des-iodo flubendiamide (hereafter "des-iodo"), 2) to determine whether EPA had properly evaluated the studies and data and had selected the correct toxicity study results (endpoints) for its risk determination, and 3) to determine whether EPA's proposed cancellation of flubendiamide due to potential risks to benthic invertebrates was based on sound science. In my analysis, I have considered the ecological risk assessments published by EPA, including recent assessments issued in support of its January 29, 2016 Decision Memorandum, the benthic invertebrates toxicity study reports for flubendiamide and des-iodo, and the guidelines, publications, and other materials cited in this Declaration.

III. SUMMARY OF CONCLUSIONS

8. My analysis focused on the issue of the potential chronic risk posed by flubendiamide and des-iodo in sediment pore water to benthic invertebrates, which is the only significant risk issue identified by EPA in its Notice of Intent to Cancel the flubendiamide registrations and the Decision Memorandum explaining its cancellation determination. After review of the relevant documents, studies, and data, and for the reasons described in this Declaration, it is my opinion that EPA's assessment of the risk posed to benthic aquatic invertebrates is fundamentally flawed. Therefore, the Agency's decision to cancel on that basis is not supported by the science.

9. More specifically, based on my analysis I conclude that:

- EPA justifies cancellation of the flubendiamide registrations based on a toxicity endpoint for benthic invertebrates of 0.28 μg/L of des-iodo in sediment pore water (i.e., the water in the spaces between sediment particles). This endpoint was derived from a spiked water study that is not relevant for des-iodo and was superseded by a subsequently conducted and more relevant spiked sediment study.

- The des-iodo spiked water study assesses the potential impacts of an exposure route, spray drift, which is not a significant route of exposure for flubendiamide, and is irrelevant to des-iodo.

- The spiked water study has other flaws, including a flawed statistical analysis that, if corrected, would lead to a higher endpoint.

- Prior EPA statements, OECD guidance, and sound scientific considerations confirm that the spiked sediment study is more relevant and the preferred approach to analyzing the potential impacts of flubendiamide and des-iodo on benthic invertebrates.

- The spiked sediment study mimics the potential gradual buildup of des-iodo that could occur over time in sediment and sediment pore water, as a result of flubendiamide partitioning to sediment and degrading to des-iodo.

- EPA's decision documents provide no explanation or rationale for their decision to regulate flubendiamide based on the des-iodo spiked water endpoint, rather than the more relevant and scientifically sound des-iodo spiked sediment endpoint.

- The des-iodo pore water chronic toxicity endpoint based on the spiked sediment study was calculated by EPA to be 19.5 μg/L, which is 70 times higher than the spiked water endpoint EPA wrongly relies on.

- Observed des-iodo pore water concentrations in water bodies close to flubendiamide-treated fields after five years of monitoring and seven years of product use do not come close to the sediment pore water endpoint of 19.5 μg/L and thus, pose no risks of concern.

- EPA's risk assessments for flubendiamide and des-iodo provide no reliable scientific basis to conclude that benthic invertebrates are at significant risk from the continued registration and use of flubendiamide products.

IV. BACKGROUND

10. Flubendiamide is a selective, non-systemic insecticide that has been approved by EPA for a variety of uses, including alfalfa, Brassica leafy vegetables, Christmas trees, corn, cotton, cucurbit vegetables, fruiting vegetables, grapes, leafy vegetables, legume vegetables, low-growing berries, peanuts, pistachio, pome fruit (e.g., apple, pear), sorghum, stone fruit (e.g., apricot, cherry, peach), sugarcane, sunflower, safflower, tobacco, tree nut crops (e.g., almond, cashew, pecan, walnut), and others. Flubendiamide is used to control lepidopteran pests at the

larval and adult stages, including armyworms, bollworms, corn borers, cutworms, fruitworms, hornworms, leaf rollers, loopers, moths, and many others. There are several formulations of flubendiamide that may be applied by ground spray, aerial spray and/or chemigation (i.e., application through an irrigation system) depending on the formulation and use pattern.

11. Flubendiamide is a member of the diamide class of chemistry. Flubendiamide targets the insect ryanodine receptor binding site, a site of little importance in mammals, and interferes with the calcium release channel.[1] As a result, flubendiamide is selectively toxic to insect pests, but has very low toxicity to humans and other mammals.

12. On March 1, 2016, EPA announced its intent to cancel the registration of four pesticide products containing the active ingredient flubendiamide.[2] In its Notice of Intent to Cancel (NOIC), EPA explained that it was seeking cancellation based on a determination that continued registration of flubendiamide products "will result in unreasonable adverse effects on the environment."[3] The NOIC and the January 29, 2016 Decision Memorandum cite concerns about flubendiamide's mobility, persistence, and potential to accumulate, and "the extremely toxic nature of the primary degradate NNI-001-des-iodo [des-iodo] to invertebrates of aquatic systems."[4] My analysis is focused on the potential toxicity of flubendiamide and des-iodo to aquatic invertebrates and whether EPA's assessment of toxicity endpoints is consistent with sound science.

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[1] J.E. Casida, *Golden Age of RyR and GABA-R Diamide and Isoxazoline Insecticides: Common Genesis, Serendipity, Surprises, Selectivity, and Safety*, 28(4) Chem. Res. Toxicology 560-66 (2015).

[2] Exhibit 19.

[3] Exhibit 20 at 11,559.

[4] *Id.*; *see also* Exhibit 30 at 1.

13. In the text that follows, I begin with a general overview of how EPA conducted its aquatic invertebrates assessment for flubendiamide and des-iodo. I then proceed with specific comments on the available sediment toxicity studies for benthic invertebrates and EPA's rationale for selecting the effects metrics for their assessment from these studies.

V. EPA'S AQUATIC INVERTEBRATE RISK ASSESSMENTS

A. EPA's Ecological Risk Assessments Have Focused on Potential Risks to Benthic Aquatic Invertebrates.

14. EPA's Environmental Fate and Effects Division (EFED) assessed the ecological risks of flubendiamide and des-iodo in three risk assessments conducted in support of the original flubendiamide registrations in June 2008 and in support of the expansion of the registrations to cover new crops and uses in May 2010 and December 2010.[5] In connection with its January 29, 2016 cancellation determination, EPA issued an ecological risk assessment addendum to address new studies and data that had been received and discussions and evaluations of flubendiamide that had occurred since the December 2010 risk assessment.[6]

15. In its flubendiamide risk assessments, EPA has repeatedly confirmed that there are no direct risks of regulatory concern with respect to mammals, birds, fish, crustaceans, mollusks, beneficial insects, bee pollinators, and plants.[7]

16. The ecological concern behind EPA's January 29, 2016 cancellation determination and the March 4, 2016 NOIC is the potential for chronic risk to aquatic

[5] Exhibit 27 (EFED Risk Assessment for the Section 3 New Chemical Registration of Flubendiamide (June 23, 2008)); Exhibit 28 (EFED Risk Assessment for Legume Vegetable and Christmas Tree New Uses for the Insecticide Flubendiamide); Exhibit 29 (EFED Ecological Risk Assessment for the New Use of Flubendiamide on Alfalfa and Certain Other Crops).

[6] Exhibit 31 (EFED Flubendiamide Ecological Risk Assessment Addendum (Jan. 28, 2016)).

[7] Exhibit 27 at PDF p. 2; Exhibit 28 at 3-8 (PDF pp. 22-27); Exhibit 29 at 38-41.

invertebrates.[8] More specifically, EPA's concern is that flubendiamide and des-iodo would "accumulate in aquatic systems" over time, "eventually exceeding Agency LOCs [levels of concern]" and creating "a potential for risk to benthic [bottom-dwelling] invertebrates."[9]

17. In its original three ecological risk assessments, EPA assessed potential risk to aquatic invertebrates with a screening-level (Level 1) risk assessment in which acute and chronic estimated environmental concentrations (EECs) in overlying and benthic pore water and bulk sediment were compared to corresponding effects endpoints (e.g., LC50 [concentration causing 50% mortality] for acute effects, NOEC[10] [No observed effects concentration] for chronic effects) for aquatic invertebrates. This analysis results in a risk quotient (RQ, i.e., Acute RQ = EEC/LC50 and chronic RQ = EEC/NOEC) to quantify the potential risk. EPA compares each risk quotient to the corresponding Level of Concern (LOC, e.g., LOC for acute risk to endangered aquatic species = 0.05, LOC for chronic risk to all species = 1). Separate analyses were conducted for flubendiamide and des-iodo. EPA's recent addendum was conducted after the generation of higher-tier, more relevant data, including five years of real-world monitoring data and more environmentally relevant toxicity data.

18. As described in Dr. Engel's declaration, EPA's most recent risk assessment addendum fails to properly reflect the higher-tier, real-world monitoring data, and its

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[8] Exhibit 30 at 10; Exhibit 20 at 11,559.

[9] Exhibit 30 at 3.

[10] In its assessments and data evaluation records, EPA uses the terms "No Observed Effect Concentration" (NOEC) and "No Observed Adverse Effect Concentration" (NOAEC) interchangeably. The two terms have slightly different meanings as a NOEC may also be derived for beneficial effects. To avoid confusion herein, I will use the NOEC nomenclature throughout.

environmental exposure estimates are based on overly conservative, theoretical modeling that does not accurately reflect or predict real-world exposures.

19. As discussed below, EPA's most recent risk assessment addendum likewise incorrectly ignores the results of more relevant toxicity data, resulting in a toxicity endpoint that is far lower than the science supports. For the reasons discussed below, EPA's proposed cancellation of flubendiamide based on the spiked water endpoints is not supported by the current science.

B. EPA Has Identified No Regulatory Risks of Concern for Aquatic Invertebrates Other Than Potential Chronic Risks to Benthic Invertebrates.

20. Acute and chronic toxicity tests involving aquatic invertebrates have been conducted for flubendiamide and des-iodo.

21. Testing conducted on *Daphnia magna* to evaluate the potential impacts on water column dwelling (i.e., non-sediment dwelling) aquatic invertebrates to an acute exposure to flubendiamide and des-iodo and chronic exposure to flubendiamide all showed no observed adverse effects at concentrations up to their limits of solubility (29.9 μg/L for flubendiamide and 187 μg/L for des-iodo).[11] Similarly, the following sediment dwelling species experienced no adverse effects to flubendiamide exposure concentrations of 30 μg/L or des-iodo concentrations of 200 μg/L following acute exposures in water only trials: *Lumbriculus variegatus*, *Hyalella azteca*, *Centroptilum triangulifer*, *Chironomus tentans* and *Chironomus riparius*.[12] Because concentrations of flubendiamide and des-iodo in water in the environment are limited by their

[11] Exhibit 29 at 24.

[12] S. Thomas and H.O. Krueger, Wildlife International, Ltd., Benthic Organism Acute Toxicity Screens for Flubendiamide and NNI-0001 des-iodo, Bayer Study No. EBAMY010 (2010).

solubility, these studies indicate that the tested species could not be at acute risk in the environment as a result of exposure to flubendiamide or des-iodo in the overlying water.

22. Acute and chronic toxicity testing of *D. magna* using formulated products showed risk quotients that exceeded EPA's LOCs for some use patterns.[13] However, as EPA has recognized, chronic exposure is not a concern for the formulated products because the products do not persist in their formulations in the aquatic environment. Acute exposure to formulated products is likewise not a source of significant regulatory concern. As EPA confirmed in the January 29, 2016 Decision Memorandum, "[t]he acute risk issue is relatively minor and refers to enhanced toxicity of the formulations" which is "applicable only to direct application to aquatic environments through spray drift."[14] However, spray drift exposure from flubendiamide is not a significant concern, because "most of the contributions to aquatic environments are from means other than spray drift (runoff and erosion)."[15]

23. The above indicates that flubendiamide and des-iodo pose no risks to water column dwelling (i.e., non-sediment dwelling) invertebrates.

24. This analysis focuses on potential chronic risk concerns for benthic (sediment dwelling) invertebrates exposed to flubendiamide and des-iodo in sediment pore water, because those risks have been identified by EPA as the only significant ecological risks of concern and are the risks that EPA relies on to justify its cancellation determination.[16] EPA's effects endpoints for benthic aquatic invertebrates are lower for des-iodo than for flubendiamide, and EPA's calculated RQs for des-iodo are higher.

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[13] Exhibit 27 at pp. 53-54; Exhibit 28 at p. 42-43; Exhibit 29 at 29-30.

[14] Exhibit 30 at 3.

[15] Exhibit 27 at 68.

[16] *See, e.g.*, Exhibit 30 at 10.

25. In estimating chronic risk of flubendiamide and des-iodo to sediment dwelling aquatic invertebrates, EPA relied on the results of spiked water studies for the midge, *Chironomus riparius*. As discussed below, it is my opinion that EPA's reliance on the results of the spiked water studies to evaluate chronic risk to benthic aquatic invertebrates, rather than the subsequent, more relevant spiked sediment studies, is not scientifically justified. As a result, EPA's risk assessments for flubendiamide and des-iodo are flawed, and provide no reliable scientific basis to conclude that benthic invertebrates are at significant risk from the continued registration and use of flubendiamide products.

VI. DERIVATION OF BENTHIC AQUATIC ENDPOINTS FROM THE SPIKED WATER AND SPIKED SEDIMENT STUDIES

A. Background

26. EPA asked Bayer CropScience to conduct chronic toxicity testing on the degradation metabolite des-iodo in support of the original registrations of flubendiamide, because initial toxicity studies suggested that des-iodo might be more toxic than the parent compound flubendiamide for some receptor groups, e.g., sediment dwelling invertebrates.

27. Following a standardized guideline for toxicity testing is important to ensure that the results of the study are accurate and of the highest quality. To date, EPA has not published guidelines for the conduct of chronic sediment testing.[17] The Organisation for Economic Co-operation and Development (OECD) has published guidelines for the conduct of standardized toxicity studies, including chronic sediment studies.[18]

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[17] Exhibit 44 at 11 (EFED Memorandum re Toxicity Testing and Ecological Risk Assessment Guidance for Benthic Invertebrates (Apr. 10, 2014)).

[18] OECD Guidelines for the Testing of Chemicals, Section 2, available at http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals_chem_guide_pkg-en (last visited Apr. 8, 2016).

28. Bayer CropScience generated two chronic sediment toxicity studies involving exposure of the midge, *C. riparius*, to des-iodo: one in which overlying water was spiked (hereafter referred to as "the spiked water study"), which was submitted in support of the original registrations,[19] and one in which sediment was spiked (hereafter referred to as "the spiked sediment study"), which was conducted and submitted in 2010.[20] Similar studies were submitted for flubendiamide.

29. The spiked water study was modeled after the OECD guideline for sediment-water chironomid toxicity tests using spiked water.[21] OECD guidelines state that spiked water studies are "intended to simulate a pesticide spray drift event."[22]

30. The spiked sediment study followed the OECD guideline for sediment-water chironomid toxicity tests using spiked sediment.[23] The OECD guideline document for the spiked sediment study states that such tests are "intended to simulate accumulated levels of chemicals persisting in the sediment."[24]

31. The spiked water and spiked sediment studies both exposed *C. riparius* individuals from their first instar through emergence and monitored time to emergence and

[19] Bayer CropScience AG, *Chironomus riparius* 28-Day Chronic Toxicity Test With NNI-001-des-iodo in a Water-Sediment System Using Spiked Water, Report No. DOM 23069 (2004) ("Spiked Water Study Report").

[20] S. Thomas et al., Wildlife International, Ltd., [14C]NNI-0001-desiodo: A Prolonged Sediment Toxicity Test With *Chironomus riparius* Using Spiked Sediment, Final Report, Bayer Study No. EBAMY006 (2010) ("Spiked Sediment Study Report").

[21] Exhibit 45 (OECD Guidelines, Test No. 219: Sediment-Water Chironomid Toxicity Test Using Spiked Water (Apr. 13, 2004)).

[22] *Id.* at 1.

[23] Exhibit 46 (OECD Guidelines, Test No. 218: Sediment-Water Chironomid Toxicity Test Using Spiked Sediment (Apr. 13, 2004)).

[24] *Id.* at 1.

survival of both males and females. Because the chronic RQs are higher for des-iodo compared to the parent compound, and because the des-iodo RQs are driving EPA's cancellation decision, the remainder of this section focuses on des-iodo. Many of the points, however, also apply to the flubendiamide studies.

32. In the spiked water study for des-iodo, the reported No Observed Effect Concentration (NOEC) for the most sensitive endpoint (percent emergence) was 4 µg/L des-iodo in the overlying water. This value is based on the nominal concentrations of des-iodo added to the overlying water.

33. However, EPA chose to use the analytical data from the spiked water study to calculate a time-weighted average (TWA) NOEC for des-iodo in sediment pore water of 0.28 µg/L.[25] The NOEC of 0.28 µg/L for des-iodo in sediment pore water derived from the spiked water study is the most sensitive endpoint for aquatic invertebrates,and EPA's cancellation determination is based on predicted exceedances of this NOEC.

34. The calculation of a TWA NOEC for des-iodo in sediment pore water for a spiked water study is not supported by sound science. As noted by the European Commission, spiked water NOECs should be calculated for overlying water and then compared to estimated concentrations in that compartment.[26] This is because at the outset of the test, concentrations in overlying water vastly exceed the concentrations in pore water and thus any observed toxicity is likely the result of exposure to overlying water. Including the largely irrelevant, very low initial concentrations in sediment pore water in the TWA calculation skews the NOEC downward. The

[25] Exhibit 33 at 15 (Des-iodo Spiked Water Study Data Evaluation Record (May 21, 2008)).

[26] Exhibit 47 at 18 (European Commission, Working Document: Guidance Document on Aquatic Toxicology (Oct. 17, 2002)).

spiked water study may be used to study partitioning behavior over time from overlying water to sediment and sediment pore water, but it was never intended to derive toxicity endpoints for sediment and pore water.

35. As noted above, the spiked sediment study was conducted specifically to assess potential toxicity to sediment dwelling invertebrates in sediment pore water due to the potential accumulation of des-iodo residues over time. The reported NOEC for des-iodo in the spiked sediment study based on measured concentrations (consistent with OECD guidance and standard practice) was 22 μg/L of des-iodo in sediment pore water, which was the highest level tested. The actual level at which impacts on benthic invertebrates begin to occur was not determined in the study and could be significantly higher.

36. In reviewing this study, EPA again chose to calculate a TWA endpoint, resulting in a somewhat lower NOEC of 19.5 μg/L of des-iodo in sediment pore water.[27] This EPA-calculated NOEC is approximately 70 times higher than the NOEC of 0.28 μg/L EPA derived from the less relevant spiked water study.

37. The spiked water study has major flaws that should have precluded its use in the des-iodo risk assessment for benthic invertebrates. As discussed in Section B below, the flaws include, most significantly, the use of an exposure route quite different from what would occur in real-world conditions, resulting in significant overestimation of toxicity and risk. The spiked water study also used inappropriate statistical analyses and laboratory conditions that differ from those specified in OECD guidelines. As discussed below, a more appropriate and scientifically relevant spiked sediment study is available and should have been used in the benthic invertebrates risk assessment for des-iodo.

[27] Exhibit 34 at 14.

B. EPA's Reliance on the Pore Water NOEC from the Spiked Water Study Is Not Scientifically Sound.

1. The spiked water study is not the most relevant study to determine potential effects on benthic invertebrates for des-iodo.

38. As noted above, the OECD guideline document for spiked water studies states that such tests are "intended to simulate a pesticide spray drift event," whereas the OECD guideline for spiked sediment studies states that those tests are "intended to simulate accumulated levels of chemicals persisting in the sediment."[28] Because the primary concern identified by EPA is the potential accumulation of flubendiamide and its degradate des-iodo in sediment and sediment pore water, the spiked sediment study is the more relevant and scientifically correct study to measure potential effects to sediment dwelling invertebrates.

39. EPA previously agreed with this point. For example, in its May 2008 review of the spiked water study, EPA identified as a "Major Guideline Deviation" the fact that "[o]verlying water was spiked," noting that EPA "prefer[s] that the sediment is spiked."[29] As a result, Bayer conducted a study using the preferred and more relevant spiked sediment approach, resulting in a sediment pore water NOEC of 19.5 μg/L (EPA calculated) or 22 μg/L (derived in the study report). However, EPA decided in its final risk assessment addendum supporting the cancellation decision to revert to the superseded and scientifically less sound NOEC of 0.28 μg/L from the spiked water study.

40. The greater relevance and reliability of the spiked sediment study is confirmed when one considers the characteristics of flubendiamide and des-iodo and their behavior in the environment.

[28] Exhibit 45 at 1; Exhibit 46 at 1.

[29] Exhibit 33 at 2.

41. Flubendiamide degrades slowly under laboratory and field conditions.[30] The two major degradation routes, aquatic and soil photolysis and anaerobic aquatic metabolism, could not occur during spray drift. Using the pesticide spray drift route of exposure for des-iodo is inappropriate because flubendiamide cannot degrade to des-iodo during spray drift prior to entering the aquatic environment.

42. Further, runoff of des-iodo to aquatic systems in large spikes is highly unlikely given the very slow degradation rate from the flubendiamide parent compound to des-iodo in soil. Des-iodo has, in fact, only been detected in minor amounts in the top soil layers in three field dissipation studies.[31] Thus, runoff is likely to contribute small pulses of des-iodo to water bodies over extended periods of time rather than large, short-term spikes. As described in Dr. Engel's Declaration, monitoring studies conducted by Bayer CropScience in a Georgia pond demonstrated that des-iodo concentration maxima occurred several months after flubendiamide concentrations peaked. Such a result is a strong indication that des-iodo in the sediment was the result of slow degradation of the parent compound in sediment rather than transport to aquatic systems by spray drift or runoff events shortly after application.

43. In summary, OECD guidance, EPA's own assessments, and sound science dictate that the spiked sediment study is the most relevant and scientifically sound study for measuring potential toxic effects of des-iodo through agricultural runoff and degradation. EPA's reliance

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[30] Exhibit 27 at 12 (PDF p. 17); Exhibit 28 at 10 (PDF p. 29).

[31] P. Babczinski, Bayer CropScience AG, Outdoor Soil Degradation of 14C-NNI-0001, Study No. M1251280-9 (2004); H. Reiner, Bayer CropScience AG, Metabolism of [phthalic acid ring-UL-14C]NNI-0001 in Confined Rotational Crops, Report MEF-008/03, DOMA Edition No. MO-04-009109 (2004); H. Reiner, Bayer CropScience AG, Metabolism of [aniline ring-UL-14C]NNI-0001 in Confined Rotational Crops, Study No. M 1301192-7 (2004).

on the NOEC of 0.28 μg/L from the spiked water study to justify its cancellation determination is not scientifically sound.

2. The des-iodo pore water endpoint derived from the spiked water study seriously overestimates potential effects on sediment dwelling invertebrates.

44. The use of a simulated spray drift event to derive a sediment pore water NOEC for *C. riparius* larvae exposed to des-iodo in pore water seriously overestimates potential toxicity.

45. Spiking water with a pesticide results in high concentrations in the overlying water immediately following test initiation. The concentrations in overlying water then decline as the compound moves into the sediment compartment. Indeed, measured concentrations in the spiked water study demonstrated highest concentrations of des-iodo in overlying water on Day 0 of the spiked water study followed by a steady decline to roughly one third of initial concentrations by Day 28.[32] Conversely, concentrations in sediment pore water were low initially, followed by a peak on Day 7 and slow decline to Day 28.[33]

46. This is significant because sediment-water studies evaluate overall toxicity of the system and are not designed to provide toxicity endpoints for each of the overlying water, pore water, and bulk sediment media. The exposure route in sediment-water studies dictates which toxicity endpoint is the most meaningful. In the case of spiked water studies, the exposure route being evaluated is spray drift added to the overlying water. Thus, for this type of study and according to the OECD guidelines, it is the overlying water NOEC that is the most meaningful endpoint. Analytical pore water measurements are useful to help understand the partitioning

[32] Spiked Water Study Report at 19-20.

[33] *Id.*

behavior of pesticides over time from the overlying water to sediment and sediment pore water. However, pore water NOECs in spiked water studies are of little relevance and not based on sound science. Not surprisingly, when overlying water is a much less important route of exposure, as in the spiked sediment study, the sediment pore water NOEC increased at least 70-fold to ≥19.5 μg/L.[34] Previous studies, e.g., Lydy et al. (1990) with carbaryl, parathion and aldicarb,[35] have similarly found much increased toxicity for pesticides introduced via spiked water rather than spiked sediment in sediment bioassays with *C. riparius*.

47. EPA's reliance on the pore water NOEC derived from the spiked water study significantly overestimates the toxicity of des-iodo by measuring the wrong route of exposure, and results in an endpoint that is not relevant to the exposure that would occur in the real world.

3. The spiked water study has methodological flaws that further undermine its usefulness and reliability.

48. In addition to an inappropriate route of exposure, the spiked water study contains methodological errors that undermine the accuracy of the reported NOEC.

49. First, the statistical analysis reported in the study incorrectly combined data from two sets of controls to increase the statistical power of the study. Two control treatments are necessary when a chemical is poorly soluble in water and must be dissolved in a solvent to reach experimental concentrations. The purpose of the solvent control is to verify that the solvent did not have an additional effect on exposed organisms.[36]

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[34] Exhibit 34 at 2.

[35] M.J. Lydy et al., *Effects of Sediment and Route of Exposure on the Toxicity and Accumulation of Neutral Lipophilic and Moderately Water Soluble Metabolizable Compounds in the Midge, Chironomus riparius*, *in* 13 Aquatic Toxicology and Risk Assessment 140-64 (W.G. Landis and W.H. van der Schalie eds., 1990).

[36] Exhibit 45 at 4-6.

50. OECD guidelines do not allow combining of data from no-solvent and solvent-control treatments. This type of post hoc data manipulation is unacceptable in statistics, wherein hypotheses must be stated before data are collected.[37] Statistical modifications must be made to the level at which significance is determined when post hoc comparisons are made, due to the increased likelihood of falsely rejecting the null hypothesis. In this case, a Holm-Bonferroni correction should have been applied to the p-value.[38] This correction using the William's multiple sequential t-test (i.e., the test used by the study authors) would have doubled the NOEC for des-iodo in overlying water in the spiked water study to be 8 μg/L, rather than the 4 μg/L NOEC reported in the study.

51. Second, the control treatments, which each had 4 replicates, were combined after statistical comparison with the Student's t-test. OECD guidelines state that a Student's t-test must include at least 6 replicates for each treatment for the test to be valid. With fewer than the recommended number of replicates, statistical power is reduced, thus reducing the likelihood of finding a significant difference between no-solvent and solvent-control treatments.

52. Third, in the original analyses, the no-solvent and solvent-control results were inappropriately statistically compared to exposure treatment results using William's multiple sequential t-test. This test allows multiple means to be compared to a single value (i.e., the control), but requires that all results trend in a monotonic manner (i.e., magnitude of effect

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[37] J.H. Zar, Biostatistical Analysis (5th ed. 2010).

[38] H. Abdi, *Holm's Sequential Bonferroni Procedure*, *in* 2 Encyclopedia of Research Design 573-77 (N. Salkind ed., 2010).

increases as treatment concentration increases).[39] However, the spiked water study with des-iodo did not have a monotonic concentration-response relationship for the most sensitive endpoint (i.e., percent emergence), and therefore using William's test to analyze the data was inappropriate.[40] A more appropriate statistical test for this scenario is Dunnett's test.[41] When the data are analyzed using Dunnett's test, with the control treatments separated, the NOEC for des-iodo in overlying water is 8 µg/L, twice the NOEC in the original analyses.

53. Fourth, the OECD guidelines provide specific instructions regarding study conditions in sediment toxicity studies, e.g., sediment composition and provision of food to test organisms. The spiked water study had several issues in this regard. For example, the OECD guidelines specify that the peat in the sediment must have a pH of 5.5-6.0 and be air dried.[42] The spiked water study used peat that had a pH of 2-4, and no mention was made of how the peat was dried. In addition, the OECD guidelines specify provision of 0.25-0.5 mg of fish food/day/chironomid larvae for the first 10 days of the test and 0.5-1 mg of fish food/day/chironomid larvae for days 11 to 28.[43] In the spiked water study, feeding rates were 1 mg of fish food/day/chironomid larvae each day of the study. The impact of the departures from OECD guidelines with regard to sediment pH and feeding rate are unknown, but it is possible

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[39] F. Bretz and L.A. Hothorn, *A Powerful Alternative to William's Test With Application to Toxicological Dose-Response Relationships of Normally Distributed Data*, 7(2) Envtl. & Ecological Stat. 135-54 (2000).

[40] *Id.*

[41] OECD, Current Approaches in the Statistical Analysis of Ecotoxicity Data: A Guidance to Application at 37, 42, 58 (May 9, 2006)).

[42] Exhibit 45 at 3.

[43] *Id.* at 7.

that the behavior, bioavailability and toxicity of des-iodo to chironomids may have been affected.

C. The Spiked Sediment Study Is the Correct Study to Gauge Potential Toxic Effects to Benthic Aquatic Invertebrates.

54. As discussed above, the OECD guideline for sediment-water chironomid toxicity tests using spiked sediment states that these tests are "intended to simulate accumulated levels of chemicals persisting in the sediment," and EPA previously identified the spiked sediment study as its preferred approach for these purposes as well.[44] The spiked sediment study for des-iodo followed the appropriate exposure regime for des-iodo because the degradate would potentially accumulate slowly over time in the sediment rather than arriving as a pulse in the overlying water from spray drift or runoff events shortly after application. Sediment pore water exposure would cease following adult emergence to the terrestrial environment.

55. According to EPA, the TWA NOECs for the des-iodo spiked sediment study were 7.18 μg/L in overlying water, and 19.5 μg/L in sediment pore water.[45] The study report, consistent with the OECD reporting guidelines, reports a slightly higher NOEC of 22 μg/L in sediment pore water based on mean, measured concentrations. However, the actual NOECs in the spiked sediment study are likely higher than all of these values because no effects were observed at *any* test concentration for any endpoint including mortality, mean development time, mean emergence ratio or development rate.[46]

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[44] Exhibit 46 at 1; Exhibit 33 at 2.

[45] Exhibit 34 at 2 (Des-iodo Spiked Sediment Study Data Evaluation Record (July 19, 2011)).

[46] Spiked Sediment Study Report at 21.

56. The spiked sediment study for des-iodo, like the spiked water study, also pooled the data from blank and solvent controls for the statistical analyses.[47] However, when the proper statistical tests – either a Holm-Bonferroni p-value correction or a Dunnett's test with separate control groups – are used, the results are unchanged, i.e., no statistically significant effects occur with any endpoint for any test concentration. Thus, the time-weighted average NOEC of 19.5 μg/L calculated by EPA for des-iodo in sediment pore water[48] is unaffected.

57. The spiked sediment study for des-iodo had several minor deviations from the OECD guideline[49]: 1) ground rabbit food was used instead of flaked fish food, 2) the light intensity was 446 lux, which is below the 500 – 1000 lux range specified in the guideline, and 3) the pH of the peat component was not reported and the moisture content of the sediment was below recommended levels.

58. Control mortality in the spiked sediment study for des-iodo was less than 30%, and thus acceptable. In addition, the authors observed that unusual chironomid behaviors "were few in number and occurred in the controls as well as the treatment groups . . . [any unusual behaviors observed] were not considered to be treatment-related."[50]

59. Although the spiked sediment study has minor flaws, the flaws do not detract from the results of the study. This sentiment was echoed in the EPA's reviewer comments, i.e., "there were no significant deviations from OECD Guideline 218 that would affect the scientific soundness of this study."[51] Furthermore, the exposure route in the spiked sediment study, i.e.,

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[47] *Id.* at 16.

[48] Exhibit 34 at 2.

[49] Exhibit 46 at 6, 9.

[50] Spiked Sediment Study Report at 20.

[51] Exhibit 34 at 19.

potential accumulation in sediment pore water as a result of degradation of the parent compound, mirrors the exposure route for benthic invertebrates in aquatic systems near treated areas.

60. The time-weighted average NOEC in sediment pore water for *C. riparius* exposed to des-iodo in the spiked sediment study is 19.5 μg/L,[52] which is 70-fold higher than the corresponding NOEC of 0.28 μg/L[53] in the spiked water study. The difference may in fact be greater because no effects were observed in the spiked sediment study and thus the Lowest Observed Effect Concentration (LOEC) is unknown and the NOEC is a lower bound.

D. EPA's Decision Documents Do Not Justify or Explain the Use of the Endpoint from the Spiked Water Study.

61. The documents EPA has produced in support of its cancellation decision do not justify or explain in any transparent fashion the Agency's decision to rely on the scientifically incorrect pore water NOEC of 0.28 μg/L for des-iodo to support its cancellation determination.

62. EFED's January 28, 2016 Ecological Risk Assessment Addendum suggests that the NOEC of 0.28 μg/L was EPA's consistent position, by comparing EPA's current use of that endpoint to the June 2008, May 2010, and December 2010 risk assessments.[54] Yet those assessments were all conducted before EPA completed and released its July 2011 review of the spiked sediment study, which EPA "prefer[s]" and which results in a more scientifically relevant and much higher 19.5 μg/L endpoint.[55]

63. Although EPA's reversion to the NOEC of 0.28 μg/L in December 2015 was the subject of significant discussion between the registrants and EPA leading up to the January 29,

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[52] *Id.* at 2.

[53] Exhibit 33 at 15.

[54] Exhibit 31 at 8.

[55] Exhibit 33 at 2; Exhibit 34 at 2.

2016 cancellation determination, the January 28, 2016 EFED Addendum and the January 29, 2016 Decision Memorandum do not mention, let alone provide an explanation for, EPA's decision to regulate flubendiamide based on the superseded spiked water study.

64. Instead, both documents simply present the 19.5 μg/L endpoint from the spiked sediment study as among the "final suite" of available effects toxicity endpoints.[56] Only by examining the underlying data and modeling and comparing them to EPA's statements regarding the exceedances is it clear that EPA selected the 0.28 μg/L endpoint as an "Agency LOC" [level of concern] and the basis for its cancellation determination, while rejecting and incorrectly characterizing the 19.5 μg/L endpoint as a "[Bayer/Nichino]-suggested" endpoint with which EPA did not agree.[57] As a former regulator, and as a scientist who has spent years conducting and assessing ecotoxicological risk assessments, I found EPA's lack of discussion of this point striking. Given how critical EPA's choice of endpoint was to its cancellation determination, the Agency's lack of transparency about how and why that endpoint was selected is troubling.

E. EPA Did Not Follow Its Own Guidance in Extrapolating Risk Between Aquatic Compartments.

65. In EPA's "Invertebrate Terminology" document, EPA makes the following statement, "As a second policy check, EFED consulted guidance entitled 'Toxicity Testing and Ecological Risk Assessment Guidance for Benthic Invertebrates' (USEPA 2014), which suggests that endpoints from water-only toxicity tests with invertebrates are important risk evaluation tools to ascertain potential risk to sediment organisms because bioavailability into benthic organisms is largely mediated by dissolved concentrations of the toxicant in sediment pore

[56] Exhibit 30 at 5; Exhibit 31 at 9.

[57] Exhibit 30 at 7.

waters or overlying water."[58] The Invertebrate Terminology document then goes on to state, "It then follows that risk estimates based on water column environmental exposures compared with overlying water expressed endpoints from sediment toxicity tests with invertebrates would have reasonable applicability as a surrogate for risks to aquatic invertebrates existing in the water column because the dissolved water concentration of the toxicant remains the important source of exposure."[59]

66. What EPA is stating in a convoluted way is that dissolved pesticide concentrations control toxicity to both sediment dwelling and water column dwelling invertebrates and thus risk can be extrapolated between the two receptor groups. What the Invertebrate Terminology document fails to note, however, is that EPA's 2014 guidance document states that ready extrapolation of risk between water column dwelling and sediment dwelling invertebrates only applies to compounds that do not readily bind to sediment.[60] Flubendiamide and des-iodo readily bind to sediment.[61] Thus, EPA's own guidance does not support their assertion that risks can be extrapolated between water column dwelling and sediment dwelling invertebrates.

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[59] Exhibit 32 at 3.

[60] Exhibit 44 at 5.

[61] *See, e.g.*, Exhibit 27 at 28.

F. Use of the Spiked Sediment Endpoint Results in No Risks of Concern to Benthic Aquatic Invertebrates.

67. As described in the Declaration of Dr. Engel, environmental exposures to des-iodo are properly evaluated using the higher-tier, real-world monitoring data generated by the registrants at EPA's direction.[62]

68. The results of these monitoring data show that after almost five years of monitoring and the analysis of more than 1,000 overlying and pore water samples, all measured concentrations are well below even the NOEC of 0.28 μg/L for des-iodo that EPA wrongly relies on. The highest measured concentration was 0.17 μg/L, measured at a single site, which subsequently declined in later sampling at the same site. Only five pore water samples had concentrations of des-iodo at or above 0.10 μg/L. The 0.17 μg/L maximum concentration is 115 times lower than the scientifically justified NOEC of 19.5 μg/L for des-iodo in pore water from the spiked sediment study.

69. In short, when the correct NOEC from the spiked sediment study is used, chronic risk to benthic invertebrates from exposure to des-iodo in sediment pore water is far less of a concern than portrayed by EPA in recent documents. Observed concentrations in water bodies close to treated fields after five years of monitoring and seven years of product use do not come close to approaching a properly determined sediment pore water NOEC of 19.5 μg/L. In light of these results, it is questionable whether further monitoring is even necessary. The observed levels do not suggest any risks of concern that could provide a scientific basis to justify a cancellation determination.

[62] Exhibit 6 (Declaration of Bernard Engel).

VII. CONCLUSION

70. Based on the above, I conclude that EPA has no scientific basis for using the chronic pore water NOEC of 0.28 μg/L that was derived for des-iodo from the spiked water study. Instead, the chronic NOEC of 19.5 μg/L derived from the spiked sediment study should have been used. When the correct NOEC is used along with the results from the multi-year monitoring studies, chronic risk to benthic invertebrates is not a concern. Thus, EPA has no scientific basis for canceling the flubendiamide registrations.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 11th day of April, 2016

Dwayne R. J. Moore

EXHIBIT 6

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of:	)	
	)	
Bayer CropScience LP and Nichino America, Inc.,	)	FIFRA-HQ-2016-0001
	)	
	)	
Petitioners.	)	

EXPERT DECLARATION OF BERNARD ENGEL, PH.D.
<u>IN SUPPORT OF MOTION FOR ACCELERATED DECISION</u>

TABLE OF CONTENTS

I, Bernard Engel, hereby declare as follows:

I. BACKGROUND AND EXPERIENCE

1. For the past 31 years, I have taught undergraduate and graduate level courses and conducted research in hydrology, water quality, hydrologic/water quality modeling, environmental decision support systems, and soil and water conservation at Purdue University. During this time, I have held titles of Assistant Professor and Associate Professor, and currently I am Professor and Head of the Department of Agricultural and Biological Engineering. I have served as mentor and primary research advisor for 45 graduate students completing Master's of Science and Doctor of Philosophy degrees and on the research advisory committees for an additional 115 graduate students in the fields noted above.

2. I am educated and trained as an agricultural engineer with a focus on agricultural hydrology, water quality, and soil and water conservation. I hold Bachelor's of Science and Master's of Science degrees in Agricultural Engineering from the University of Illinois at Urbana-Champaign and a Doctor of Philosophy degree in Agricultural Engineering from Purdue University. I hold a Professional Engineering (PE) license in Indiana.

3. My research accomplishments in hydrology, water quality, hydrologic/water quality modeling, environmental decision support systems, and soil and water conservation are widely recognized for their quality and impact. I was named the outstanding young researcher in my professional society (American Society of Agricultural Engineers) in 1999. I received the outstanding research award from the Purdue University College of Agriculture in 1998 for my research. I was recognized as the outstanding graduate educator by the Purdue University College of Agriculture in 2006 based on research conducted by graduate students I mentor. I was recognized as a Fellow of my professional society (American Society of Agricultural and

Biological Engineers) based on career contributions in research, teaching, and leadership with research contributions.

4. I am globally recognized as a leading researcher in nonpoint source modeling based on the impact of my research in peer reviewed journal papers published in this area over the past 20 years. I have developed and improved multiple hydrologic/water quality models, including the Soil and Water Assessment Tool (SWAT), Groundwater Loading Effects of Agricultural Management Systems (GLEAMS), and Agricultural Non-Point Sources (AGNPS) model. These efforts are documented in peer reviewed journal papers.

5. I have authored more than 165 peer reviewed journal papers, 8 book chapters, and more than 250 papers published in conference proceedings and distributed at national and international meetings focused on hydrology, water quality monitoring and modeling, environmental decision support systems, and soil and water conservation. I have served on numerous Scientific Advisory Panels (SAPs) and Boards for the U.S. government in these same areas, including FIFRA SAPs on Development of a Spatial Aquatic Model (SAM) for Pesticide Risk Assessment in 2015, Problem Formulation for the Reassessment of Ecological Risks from the Use of Atrazine in 2012, and Two-dimensional Exposure Rainfall-Runoff Assessment (TERRA) Watershed Model and its Use in the FIFRA Ecological Risk Assessment for Antimicrobial Uses of Copper in 2011, among others.

6. I am an expert in, among other things, hydrology, water quality, hydrologic/water quality modeling, water quality monitoring, soil and water conservation, and environmental decision support systems. My research, teaching, and consulting activities in these areas include pesticides, nutrients, and soil erosion/sediment.

7. Exhibit 50 is a copy of my curriculum vitae further describing my qualifications, experience, and publications.

II. SCOPE OF DECLARATION

8. I was engaged by Bayer CropScience LP (Bayer) to review and evaluate the United States Environmental Protection Agency's (EPA's) assessment of current and predicted future concentrations of flubendiamide and its primary environmental degradate, des-iodo flubendiamide (hereafter referred to as des-iodo), that will occur in water bodies from the use of flubendiamide products in agriculture. More specifically, I was asked to (a) review the available monitoring and sampling data, related reports and studies, modeling, and risk assessments related to current and potential future environmental exposure to flubendiamide and des-iodo in water bodies, (b) determine whether EPA had properly evaluated the available data, (c) evaluate EPA's use of modeling to predict current and potential future flubendiamide and des-iodo concentrations, and (d) determine whether EPA's proposed cancellation of flubendiamide products based on a conclusion that concentrations have exceeded or will exceed Agency-identified levels of concern is based on sound science.

9. In my analysis, I considered EPA documents regarding flubendiamide available on EPA's flubendiamide cancellation website, additional EPA documents and Bayer documents and data provided by Bayer, including the data and results from the Bayer monitoring studies as of March 17, 2015 that were provided to EPA, more recent information and results from the ongoing monitoring studies provided by Bayer, flubendiamide and des-iodo flubendiamide data from the USGS website, and journal articles and other materials cited in this Declaration.

III. SUMMARY OF CONCLUSIONS

10. Based on my review and analysis of materials and data provided and other materials described in this Declaration, it is my opinion that EPA's assessment of current and

future environmental exposure to flubendiamide and des-iodo from the use of flubendiamide products is flawed and incorrect, and that the data and information on environmental exposures and concentrations do not support EPA's proposed cancellation decision.

11. More specifically, based on my review and analysis I conclude that:

- Basic hydrologic principles suggest flubendiamide and des-iodo will not accumulate in the environment to concentrations of regulatory concern.

- The registrants' monitoring data offer useful insight into the seasonal and annual trends of residue concentrations, showing clear signs of chemical inputs and subsequent declines that are either missed or ignored by EPA's Environmental Fate and Effects Division (EFED).

- EFED does not interpret the effects of buffers and grassed waterways in a consistent manner in their analyses, stating at times they do not impact chemical transport and at other times minimizing the regulatory value of the Georgia test site due to the presence of a grassed waterway.

- EFED modeling that EPA uses to predict current and future residue concentrations in farm ponds is wrong and erroneously over predicts environmental concentrations. Predictions of future concentrations under the modeling become irrational.

- EFED modeling neither fits the existing field data nor is there a statistical basis to suggest it has power to predict future trends.

- Statistical analysis of the EFED modeling indicates that the model has unacceptable predictive value. The mean of the observed monitoring data provides a better estimate of environmental concentrations than does the model.

- In light of the quantitative analysis confirming the unacceptable performance of the EFED modeling approach, regulatory decisions should be made based on monitoring results, not EFED's modeling.

- After almost five years of monitoring, the registrants' monitoring data show no exceedances of the toxicological endpoints identified by EPA, and no evidence that concentrations are accumulating or will accumulate to levels of concern.

- The USGS data do not show "widespread" detection or accumulation of flubendiamide and des-iodo.

- Continued monitoring is justified in this case.

IV. OPINIONS AND ANALYSIS

A. Basic Hydrologic Principles and Movement of Compounds

12. In evaluating EPA’s conclusions with respect to environmental exposures to flubendiamide and des-iodo, it is important to understand how materials that are slow to degrade (such as flubendiamide and des-iodo) or that do not degrade (such as heavy metals or phosphorus) move through the environment. Examining the hydrologic cycle provides a basis for much of the movement of constituents that move primarily with water flow as does flubendiamide. Materials move through watersheds at varying rates depending on factors including precipitation, constituent properties, and characteristics of the watershed such as soils, slopes, and land uses. These materials would typically be moved through primary pathways of runoff and associated with soil particles that are eroded and moved by the runoff. Flubendiamide and des-iodo would move primarily in surface runoff and associated eroded soil particles or sediment carried in the runoff.

13. As materials are transported through a watershed, they may be temporarily delayed. Soil initially eroded from the watershed landscape may be deposited in small channels, streams, or rivers before later being scoured and moved further through the stream and river network. Ponds and small lakes may also be sources of delays.

14. Ultimately, materials that move through the watershed will reach large water bodies (large lakes and oceans) where accumulation at very low levels may occur. Given the large volumes of water and masses of sediments in these systems and the comparatively small masses of the materials, observed concentrations will typically be very low, even if some accumulation occurs. Factors such as degradation and burying of sediment will also limit accumulation in large water bodies.

15. The above processes would be similar for metals and even for a nutrient such as phosphorus, for which there is a significant body of scientific literature. Phosphorus transport is particularly relevant to this case because, like flubendiamide and des-iodo, its equilibrium state favors relatively insoluble mineral forms that favor binding to sediment or precipitation out of the water column. Yet, phosphorus concentrations do not accumulate to infinitely large values in small water bodies and lakes, but rather phosphorus concentrations reach some plateau and fluctuate around that level depending on continued loading to the water body. *Masses* may continue to increase in the water body, including its sediment, as the materials are covered by new incoming sediment, but *concentrations* would not continue to increase unbounded.

16. The expectations for flubendiamide and des-iodo would be similar because the small masses that reach ponds or small lakes would be buried in the sediment or otherwise flow with the water exiting the pond and watershed. Contrary to this, the EFED projections and interpretation of flubendiamide and des-iodo data and model results for small ponds suggest continued increases in flubendiamide and des-iodo concentrations without bounds, which is unreasonable and seemingly impossible.

B. The Bayer Monitoring Studies Do Not Show Long-Term Accumulation of Flubendiamide or Des-Iodo.

1. Study Design and Conduct

17. Bayer has conducted almost five years of monitoring for flubendiamide and des-iodo at two sites in North Carolina and Georgia. These studies were conducted as required by EPA. EFED reviewed and approved the monitoring sites, study design, and supporting protocols prior to initiation of the monitoring studies.

18. Each site includes intermittent and perennial streams and a farm pond that receives drainage from an adjacent treated field. The field sites have the approximate properties

of EFED's "farm pond scenario," where a small pond receives its entire runoff loading from an adjacent, treated field approximately 10 times larger than the pond. EFED defines this 10:1 drainage-to-pond ratio as the reasonable worst case for exposure assessment, and results derived from these studies are intended to be protective of the greater agricultural environment.

19. Flubendiamide and des-iodo concentrations in all sampling locations at these sites have been determined approximately once per month for these constituents in the sediment, water column, and sediment pore water. Bayer has conducted monitoring at these sites for almost five years. The monitoring is ongoing. For this analysis I was provided and reviewed monitoring data available through March 17, 2015, which I understand were finalized and submitted to EPA. In addition, at my request Bayer provided information and results from the ongoing monitoring studies through October 2015, that are reflected in the Figures and discussions below.

2. The Monitoring Data Confirm Movement of Flubendiamide and Des-Iodo Through the Watershed.

20. The observed data from both of these sites show trends that are consistent with delayed movement through an agricultural watershed as described above. Monitoring data at the North Carolina and Georgia pond sites show declines in flubendiamide and des-iodo each year as these constituents move out of the ponds via water flowing through the ponds. This was confirmed at both study sites by photographs showing water flowing into an overflow pipe or over the spillway of the pond during the study period.

21. Data collected by Bayer at the Georgia and North Carolina study sites also indicate flubendiamide and des-iodo do not accumulate in the up- and downstream sampling locations. In discussing the Georgia flowing water sites, EFED agrees that flubendiamide and des-iodo will not accumulate to a substantial degree, stating that "EFED does not anticipate

continuous accumulation at these flowing-water sites because any accumulation is continuously (water) or periodically (sediment) flushed downstream."[1]

22. Under the hydrologic principles described above, flubendiamide and des-iodo will move through the watershed and ultimately reach large water bodies (large lakes and oceans). Given the small masses of flubendiamide applied in the landscape, and its degradation processes, accumulation of flubendiamide and des-iodo to levels of concern will not occur in these water bodies. A degradation pathway via photolysis for des-iodo has been identified by Bayer which provides sufficient reactivity to ensure long-term accumulation in the environment should not take place.[2]

3. The Pond Monitoring Data Do Not Show That Long-Term Accumulation Is Occurring or Will Occur.

23. The observed flubendiamide and des-iodo concentrations in the North Carolina and Georgia sites show no accumulations above levels of concern nor do they suggest that accumulations will occur reaching levels of concern, since the study has now extended to the point where the concentration plateaus for both locations are being reached or will be in the near future.

24. EPA's assumption that flubendiamide and des-iodo are accumulating based on the observed data in the North Carolina and Georgia monitoring sites is unfounded. As described below, variability in observations in North Carolina is explained by variability in flubendiamide application rates, conditions, and timing. EPA wrongly discounts the Georgia data because of the presence of grassed waterways at that site. Further, based on the sediment sampling approach to obtain pore water concentrations, until flubendiamide is present in the top 5 cm of pond

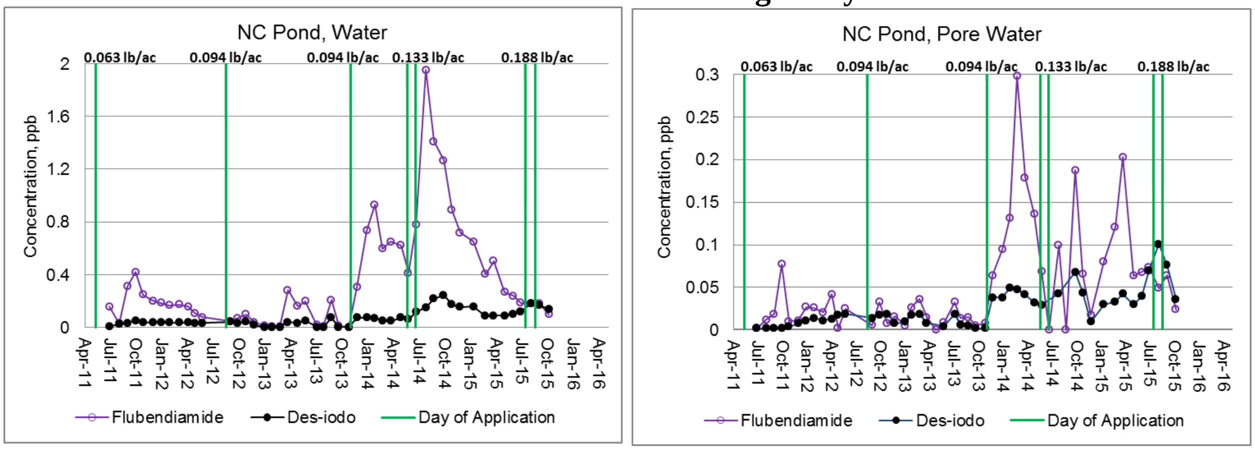
[1] Exhibit 25 at 8 (EFED Response to Bayer CropScience LP White Paper (July 15, 2015)).

[2] L.L. McConnell, Bayer CropScience, [Phthalic acid ring-UL-14C]Flubendiamide-desiodo Phototransformation in Aqueous pH 7 Buffer, Final Report, Report No. MEAMN004 (2016).

sediment, the concentrations of constituents may increase, but then would be expected to plateau. The EFED modeling does not account for any of these conditions. Likewise, EFED's use of and interpretation of trend lines fit to the observed data are incorrect for failing to account for any of these factors.

25. At my direction, Bayer updated previously produced figures showing the behavior of flubendiamide and des-iodo over time in the water column and pore water for the North Carolina and Georgia monitoring sites to include additional data through October 2015. These updated figures are provided below as Figure 1.

North Carolina Monitoring Study



Georgia Monitoring Study

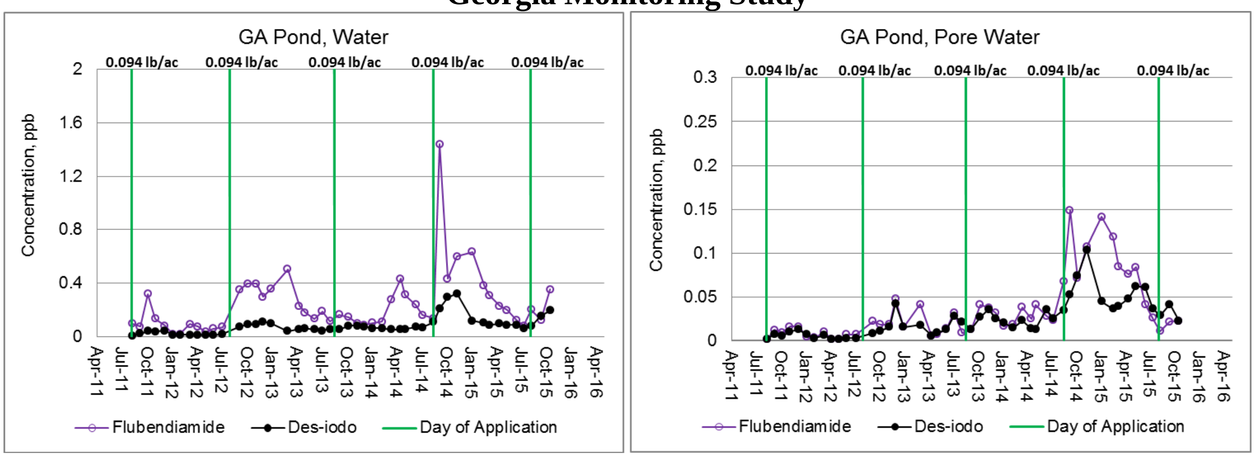


Figure 1. Monitoring results of flubendiamide and des-iodo in water column (left side) and pore water (right side) from North Carolina (top) and Georgia (bottom) ponds.

The charts in Figure 1 show measured concentrations of flubendiamide (in purple) and des-iodo (in black). The timing of Belt® (flubendiamide) applications to the pond watershed is shown by vertical lines, with the amount applied shown at the top of the chart.

26. Examination of the observed data shows several important attributes of flubendiamide and des-iodo behavior. Examining the water column and pore water data for both flubendiamide and des-iodo shows observed concentrations increasing following flubendiamide application in the watershed (as would be expected), reaching a peak, and then declining prior to the next year's application. These observed declines at both the North Carolina and Georgia

monitoring sites are largely counter to the EFED model that at best predicts only trivial declines due to pond outflow.

27. **North Carolina Site:** The observed concentrations at the North Carolina site are not evidence of a trend toward long-term accumulation as EPA suggests. Instead, the change in application rates and timing, rainfall timing and magnitude, and conditions for flubendiamide application at the North Carolina site explain much of the trend in the observed data at this site.

28. For compounds such as flubendiamide, movement of the material in runoff and with sediment is proportional to application rate, meaning that doubling of the application rate will result in doubling of its movement in runoff and sediment (assuming similar rainfall patterns). At the North Carolina site, the 2012 flubendiamide application rate was 1.5 times the rate for 2011. The application rate for 2014 was more than double that of 2011. The application in 2013 occurred under unusual circumstances that are not typical (applied in November to the ground without an actively growing crop) and represent conditions of high potential for movement of the material with runoff and sediment. Timing and magnitude of rainfall following field application of flubendiamide further explain magnitudes of movement with runoff and sediment to the pond as well as declines in concentrations in the water column as water flows through the pond. The parameterization of the EFED model in the manner in which it was applied at the North Carolina site does not appropriately account for these factors.

29. The concentrations of flubendiamide and des-iodo would be expected to increase at the North Carolina monitoring site based on the factors discussed above, rather than its chemical properties. Thus, EFED’s conclusion that the data show long-term accumulation as predicted by EPA’s model has no basis; the increased concentrations observed are explained by increased application rates, field conditions at the time of the 2013 application, and rainfall

magnitude and timing. Further, as described below in the section on statistical analysis of the model, the suggestion that the EFED model matches observed data at the North Carolina site is incorrect.

30. **<u>Georgia Site</u>:** The Georgia monitoring data also show increases in flubendiamide and des-iodo concentrations in the water column and in sediment pore water following field application. The concentrations reach a peak and then decline until an application in the following year. The variability from year to year is much less at the Georgia site than at the North Carolina site. The flubendiamide application rate and timing each year are consistent for the Georgia site, while these were not consistent for the North Carolina site as discussed above.

31. EFED discounts use of the Georgia data throughout their analysis as the magnitude of these data remain more uniform over time and significantly below the EFED model predictions. EFED attempts to attribute this to the presence of grassed waterways, suggesting the grassed waterways are preventing flubendiamide and des-iodo from reaching the pond, even though EFED elsewhere states that grassed buffers are not effective mitigation measures for flubendiamide and des-iodo (see discussion of EPA's inconsistent position on buffers below). Grassed waterways and buffers cannot capture all runoff constituents for conditions such as those in Georgia. The magnitude of flubendiamide reaching the Georgia pond would be reduced by the grassed waterway, but the presence of grassed waterways would not prevent observation of a trend should one exist. In summary, the Georgia pond experiment informs the exposure assessment by again confirming the constituents decline seasonally with trends that cannot be captured by the EFED model.

32. **<u>Sediment Layering</u>:** Any observed increases in pore water flubendiamide and des-iodo concentrations in the monitored data at the Bayer monitoring sites to date can also be

explained by the sediment pore water sampling methodology. Pore water is sampled from the top 5 cm of sediment. A 5 cm depth of sediment in these ponds would represent sediment reaching the pond over some period of time, likely several years or more. Thus, as new sediment containing flubendiamide and des-iodo is deposited in a pond, the pore water concentration of these constituents would be expected to increase until 5 cm of sediment was deposited that contained these constituents. Beyond this period, pore water concentrations would plateau and fluctuate around the plateau value based on amounts of constituents represented in the most recent 5 cm of sediment (recall the phosphorus trends discussed above).

33. This layering of constituents in the sediment will preclude the continued growth in constituent concentrations in sediment pore water predicted by EFED's model. Constituents in sediment below the top 5 cm of sediment will be buried and unavailable to contribute to concentrations in the top 5 cm of sediment pore water. Ultimately, however, the pond sediment and any materials in the pond sediment would be scoured and continue downstream, moving through the watershed as described above.

4. The Stream Monitoring Data Confirm Movement Through the Watershed and Do Not Show Accumulation.

34. The Bayer monitoring studies also include samples from intermittent and perennial streams, and provide samples of upstream water (control samples) prior to being influenced by the test site and downstream water that is influenced by the test site to define exposures beyond the farm pond. Figure 2 provides concentrations of des-iodo, which is the residue of greater EFED concern, in the flowing water bodies in the monitoring study.

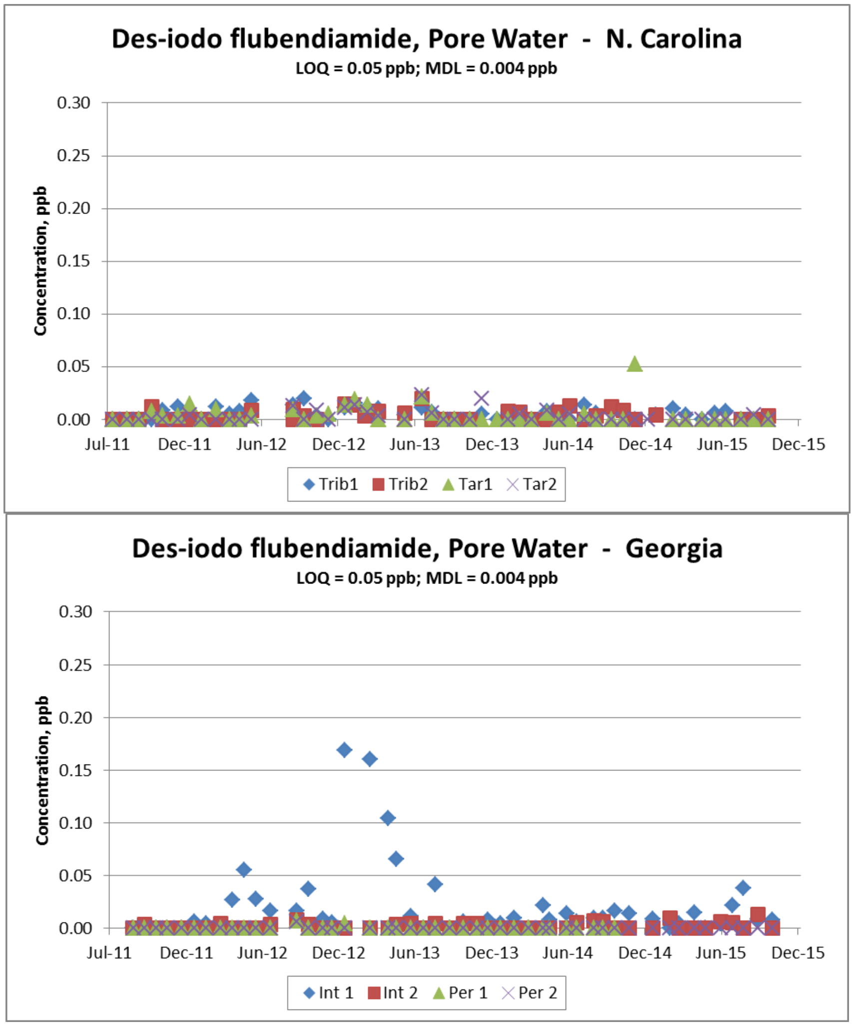


Figure 2. Des-iodo concentrations in samples taken from upstream intermittent creeks (Trib 1 / Int 1), downstream intermittent creeks (Trib 2 / Int 2), upstream perennial creeks / rivers (Tar 1 / Per 1) and downstream perennial creeks / rivers (Tar 2 / Per 2).

35. Samples taken before and after pond water flows into intermittent creeks or tributaries, and finally into larger perennial creeks and rivers confirm no evidence of accumulation; are well below any risk endpoint defined by EFED; and confirm my opinion that chemical residues will move from collection points, such as ponds, through the agricultural watershed in concentrations that do not challenge the environment.

C. The USGS Data Do Not Show That Flubendiamide or Des-Iodo Are Ubiquitous or Accumulating.

36. At EPA's request, the United States Geological Service (USGS) has tested for flubendiamide and des-iodo as part of its nationwide water monitoring program. As part of my review, I downloaded the flubendiamide and des-iodo concentration data for rivers and streams from the USGS website on March 12, 2016. The USGS data include nearly four years of monthly observations for these constituents from the fall of 2012 through the summer of 2015 for more than 90 stations, and include additional stations with smaller numbers of observations. Analyses of 5,004 samples were reported. Review of the USGS river and stream monitoring data do not suggest that flubendiamide and des-iodo are ubiquitous or accumulating. Observed levels are well below the "no effect" level.

37. EFED previously analyzed USGS data for the period of fall 2012 to October 2014; approximately one year of observations fewer than are currently available. Based on their review of the USGS data, EFED indicated that "California, Georgia, North Carolina, Mississippi, and Louisiana had multiple sites with frequent detections (Figure 1)," and referred to "widespread, non-targeted, filtered USGS detections."[3] EPA's figure showing these detections is provided as Figure 3 below.

[3] Exhibit 31 at 16 (EFED Flubendiamide Ecological Risk Assessment Addendum (Jan. 28, 2016)).

Figure 3. Flubendiamide detections in surface water samples collected by the USGS and registrant (from EPA EFED Ecological Risk Assessment Addendum (Jan. 28, 2016), Exhibit 31 at 16).

38. While the sites with what EFED termed "frequent detections" are widespread geographically, characterizing this as "widespread detections" is misleading. The three North Carolina sites that are identified as having frequent detections include two tributaries to the Neuse River and a downstream Neuse River site. The sites in Louisiana include three locations on the Mississippi River and three sites on the Atchafalaya River. Two sites with frequent detections in Mississippi are on the Yazoo River and the third is on the Mississippi River. The sites labeled with frequent detections in Georgia are small streams sampled by Bayer as part of its monitoring study, and not USGS as the supporting EPA text for the figure suggests. For the sites labeled as having infrequent detections, many of the detections were labeled by USGS as "below the reporting level but at or above the detection level" or "below the detection level."

39. Figure 4 below shows the estimated agricultural use of flubendiamide for 2013 (sourced from the USGS website referenced in the figure caption). Stream and river sites in Figure 3 characterized by EPA as having frequent detections of flubendiamide occur in areas with the greatest flubendiamide application. Note also that not all sites in areas of highest application on Figure 4 were characterized by EPA on Figure 3 as having frequent detections.

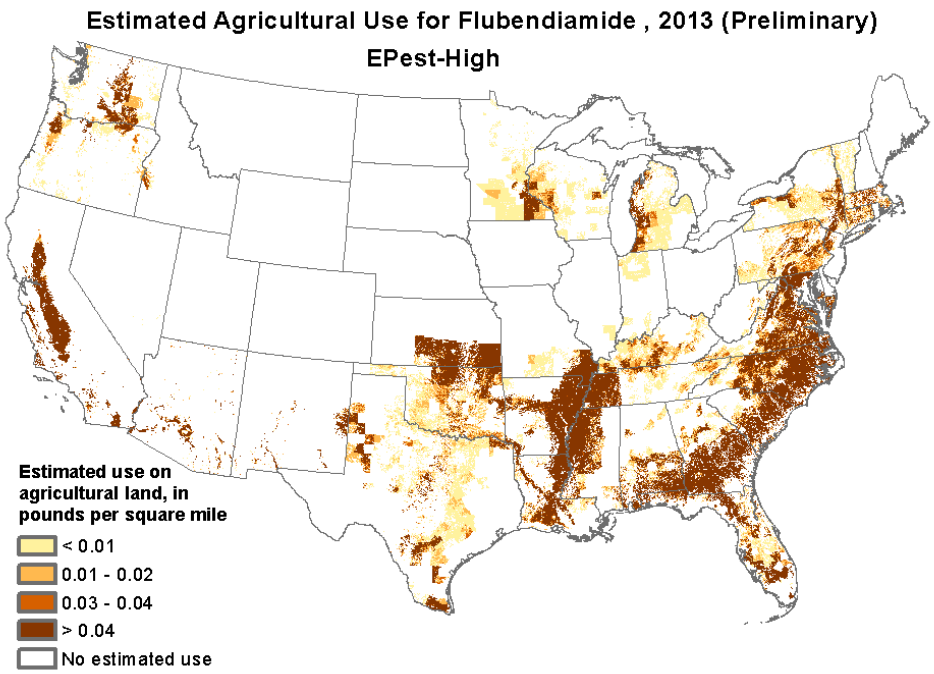


Figure 4. Estimated flubendiamide application in 2013 (from http://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2013&map=FLUBENDIAMIDE&hilo=H).

40. EFED correctly describes the USGS samples as being filtered prior to analysis and acknowledges this will attenuate the residue levels by removing sediment-bound residue. While the extent of the residue attenuation due to filtering cannot be established, the reported USGS results are similar to those reported by Bayer where filtering did not occur, suggesting the impact of filtering is small.

41. EFED incorrectly concludes that the flubendiamide and des-iodo concentrations measured in flowing water by USGS are evidence for upstream accumulation in lentic (non-flowing) water bodies.[4] This conclusion cannot be drawn from the USGS data, as one should more reasonably assume the constituent detections in the USGS data illustrate the transport of residues through the watersheds under the influence of hydrologic cycling previously described. The more reasonable source of the residues is the treated fields in the watershed, not the lentic water bodies as EFED concludes. While some fields on which flubendiamide is applied would flow into ponds before the water from the ponds flows into streams, the majority of fields in watersheds would typically flow into channels and small streams.

42. In summary, review of the USGS river and stream monitoring data show limited, low-level detections consistent with areas of product use, but do not suggest that flubendiamide and des-iodo are ubiquitous or accumulating. The data analyzed contain an additional year of data beyond those available when EFED conducted an analysis of USGS data, providing further evidence that flubendiamide and des-iodo are not accumulating and exceedances are not occurring. All values observed are below levels of regulatory concern. Further, EFED's characterization of the USGS data is misleading.

D. EPA Takes Contradictory Positions on the Effect of Buffers on Flubendiamide and Des-Iodo Runoff.

43. EFED attempts to simultaneously take the position that buffers do not work in reducing losses of flubendiamide to small ponds and that the grassed waterway works too well to consider the Georgia pond data. It is not possible to logically adhere to both of these positions simultaneously.

[4] Exhibit 36 at 2 (EFED Response to Bayer CropScience LP Flubendiamide Aquatic Risk Email Submission (July 8, 2015)).

44. As discussed above, EFED largely discounts and ignores the data from the Georgia monitoring site, where application rates each year are consistent and the resulting concentrations of flubendiamide and des-iodo are more uniform, based on the presence of a grassed waterway that was installed in the watershed.[5]

45. On the other hand, EFED has taken the position that buffers are not effective in mitigating movement of flubendiamide off fields and out of watersheds. For example, one of their "key findings" from the pond monitoring study was that "Vegetative Filter Strips (VFSs) are ineffective in preventing this accumulation in downstream waterbodies."[6] If this is EFED's position, ignoring the results from the Georgia pond site is logically inconsistent. The grassed waterway is a standard conservation practice in watersheds such as the study site in Georgia. They are used to safely convey runoff that accumulates in concentrated flow areas. Grassed waterways have some similarity to buffers in that both conservation practices are commonly used in addressing runoff issues. If anything, a grassed waterway would be expected to be less effective than a buffer in reducing flubendiamide reaching the pond, as grassed waterways are primarily designed to safely convey runoff without causing significant soil erosion in the concentrated flow path or channel, thereby preventing gullies from forming.

46. Elsewhere, while largely ignoring the Georgia data, EPA asserts that "[b]ecause the Agency's modeling does not account for the effect of VFSs, but still largely matches the monitoring data, we believe the effect of VFSs is not large enough to mitigate the ecological risks posed by flubendiamide applications."[7] This contradicts EPA's position that the grassed

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[5] *See, e.g.*, Exhibit 35 at 4-5, 13-14 (EFED Review of Water Monitoring Project (Feb. 20, 2015) (contending that the presence of grassed waterways would "reduce the accumulation of flubendiamide and des-iodo" and "confounded" the interpretation of the Georgia data).

[6] Exhibit 25 at 4.

[7] Exhibit 30 at 4 (EPA Decision Memorandum (Jan. 29, 2016)).

waterway at the Georgia site precludes use and interpretation. Moreover, as discussed below, EFED's modeling does not "largely match" monitoring data at the Georgia or the North Carolina site.

E. EPA's Modeling Does Not Perform in Predicting Flubendiamide and Des-Iodo Concentrations.

1. EPA relies on unsupported assertions that its modeling performs well.

47. EFED's review documents consistently indicate EFED's model performs well relative to the observed data. For example, EFED's February 20, 2015 review of the reports from Bayer's monitoring study includes several statements asserting that the model performs well:

- "Overall, the Agency believes the monitoring data tracks reasonably well with the modeled data."
- "The Agency believes the SWCC predictions fit the water column data quite well (Figure 6a and b)."
- "The NC pond data provide a good match to the SWCC modeling (Figures 6a and b)."[8]

48. EFED's July 15, 2015 response to Bayer's June 30, 2015 white paper states:

- "The key findings from the pond monitoring study are that: 1) flubendiamide and des-iodo accumulate in farm ponds similar to the accumulation predicted by EFED's exposure modeling; . . . Continued monitoring at these sites are unlikely to change this understanding."
- "In the North Carolina pond (which was the only pond without grassed waterways in the watershed), the concentrations of des-iodo (and flubendiamide) observed closely approximates the concentrations expected from exposure modeling."[9]

49. EFED's January 28, 2016 Ecological Risk Assessment Addendum indicates the following regarding the Georgia monitoring data:

[8] Exhibit 35 at 12, 18.

[9] Exhibit 25 at 3-4.

- "The accumulation measured in the first three years of the pond data least impacted by the identified issues largely matched the initial 3 years of concentration predictions of EFED's aquatic exposure modeling."[10]

50. EFED concludes that its model "performs quite well," despite conducting no statistical analysis to identify how well the EFED model performed with respect to monitoring data. This is contrary to the guidance in the EPA document on Guidance on the Development, Evaluation, and Application of Environmental Models that suggests comparison of modeled results with monitoring data when feasible and provides a number of quantitative methods for assessing such comparisons.[11]

51. EFED's belief that its model performs well relative to observed field data is incorrect, as demonstrated in the next section.

2. Statistical analysis shows that EFED's model does not perform well.

52. Several statistical analyses are commonly used in assessment of hydrologic and water quality models such as the model used by EFED. These commonly used statistical measures are briefly introduced, followed by their computation for the North Carolina and Georgia monitoring sites.

53. The Coefficient of Determination, or R^2, describes how well observed outcomes are replicated by the model, based on the proportion of total variation in observed data explained by the model. An R^2 of 1 indicates that the regression line or model perfectly fits the data, while an R^2 of 0 indicates that the line or model does not fit the data at all.

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[10] Exhibit 31 at 12.

[11] Exhibit 51 (EPA, Guidance on the Development, Evaluation, and Application of Environmental Models (Mar. 2009) (excerpts).

54. A common statistic used to understand the performance of hydrologic/water quality models is the Nash-Sutcliffe Efficiency (NSE).[12] The NSE indicates how well the plot of observed versus simulated data fits the 1:1 line (a line of perfect fit between a model and observed data). This is the same as the Coefficient of Determination (R^2) when the intercept is forced to be 0. NSE ranges from $-\infty$ to 1.0, with NSE = 1 being the optimal value. Values between 0.0 and 1.0 suggest the model has some predictive ability, whereas values < 0.0 indicate that the mean observed value is a better predictor than the modeled values. This would indicate that simply taking the average of the observed data would be a better predictor than applying the model, which indicates unacceptable performance of the model.

55. Percent bias (PBIAS) is another measure used to assess model performance and measures average tendency of the simulated data to be larger or smaller than their observed counterparts.[13] PBIAS is the deviation of data being evaluated, expressed as a percentage. The optimal value of PBIAS is 0.0, with small values indicating accurate model simulation. Positive values indicate model underestimation bias, and negative values indicate model overestimation bias.

56. Ranges of statistics considered acceptable for hydrologic/water quality models are highlighted in Engel et al. (2007)[14] and Santhi et al. (2001).[15] Engel et al. (2007) reviewed ranges of statistical performances for hydrologic/water quality models. Santhi et al. (2001) suggested

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[12] D.N. Moriasi et al., *Model Evaluation Guidelines for Systematic Quantification of Accuracy in Watershed Simulations*, 50(3) Transactions ASABE 885-900 (2007).

[13] *Id.*

[14] B. Engel et al., *A Hydrologic/Water Quality Model Application Protocol*, 43(5) J. Am. Water Res. Ass'n 1223-36 (2007).

[15] C. Santhi et al., *Validation of the SWAT Model on a Large River Basin With Point and Nonpoint Sources*, 37(5) J. Am. Water Res. Ass'n 1169-88 (2001).

the following NSE, R^2, and P_{BIAS} values as acceptable ranges for hydrologic/water quality model performance:

NSE > 0.50

$R^2 > 0.50$

P_{BIAS} ±25%.

57. **North Carolina Site:** The NSE, PBIAS, and R^2 were computed for EFED's modeling of flubendiamide and des-iodo concentrations in the water column and in sediment pore water at the North Carolina site using the observed data from the site. EFED modeled two cases – their standard model and an updated model considering flow through the pond. Statistics were computed for both. The results are summarized in the table below (Table 1).

Table 1. NSE, PBIAS, and R^2 for North Carolina site EFED models and monitoring data.

	North Carolina Site		
Model	**NSE**	**PBIAS (%)**	**R^2**
Flubendiamide in Water Column	-0.17	66	0.15
Flubendiamide in Water Column with Flow Through	-0.24	72	0.11
Des-iodo in Water Column	-0.22	-22	0.29
Des-iodo in Water Column with Flow Through	0.10	24	0.22
Flubendiamide in Pore Water	-0.41	-89	0.16
Flubendiamide in Pore Water with Flow Through	-0.14	-59	0.11
Des-iodo in Pore Water	-11.92	-227	0.42
Des-iodo in Pore Water with Flow Through	-3.37	-127	0.35

58. All but one of the NSE values are negative, indicating the mean of the observed data is a better predictor than the EFED model. The only model with a positive NSE is for des-iodo in the water column with flow through. However, based on suggested NSE values for hydrologic/water quality models performance, this value is well below the level for acceptable model performance (NSE > .50). Further, the PBIAS values indicate that the model greatly over predicts des-iodo in pore water even when water flow through the pond is considered.

59. In short, statistical analysis of the EFED model and monitoring data for the North Carolina site indicates that the model does not perform well. The mean of the monitoring data is a better estimate of the observed data than the model, indicating the model has no value as a predictive tool for future conditions. Given that the mean of observed data is a better predictor of observed data than both EFED models, the mean of the observed data is the best predictor of future conditions. This supports continued collection of monitoring data to evaluate future trends and to address and clarify concerns of accumulation and the use of observed monitoring data rather than EPA's modeling to guide regulatory determinations.

60. **Georgia Site:** A similar analysis was conducted for the Georgia monitoring site, which had two ponds at the site. The results are summarized in the table below (Table 2).

Table 2. NSE, PBIAS, and R^2 for Georgia site EFED models and monitoring data.

	Pond 1			**Pond 2**		
Model	**NSE**	**PBIAS (%)**	**R^2**	**NSE**	**PBIAS (%)**	**R^2**
Flubendiamide in Water Column	-4.52	-286	0.24	-2.81	-255	0.12
Flubendiamide in Water Column with Flow Through	-0.51	-121	0.28	-0.15	-103	0.10
Des-iodo in Water Column	-41.27	-661	0.50	-40.15	-748	0.32
Des-iodo in Water Column with Flow Through	0.64	-52	0.55	0.36	-70	0.30
Flubendiamide in Pore Water	-215.65	-2100	0.57	-494.69	-2888	0.34
Flubendiamide in Pore Water with Flow Through	-63.42	-1164	0.43	-149.67	-1616	0.29
Des-iodo in Pore Water	-428.14	-2310	0.59	-2478.93	-5694	0.29
Des-iodo in Pore Water with Flow Through	-21.78	-596	0.51	-152.07	-1574	0.24

61. Similar to the North Carolina site, all but one of the NSE values are negative for each pond, indicating the mean of the observed data is a better predictor than the model, and the only model with a positive NSE (des-iodo in the water column with flow through) is still well below the level for acceptable performance. The very large, negative PBIAS values indicate that

the model vastly over predicts des-iodo in pore water, even when water flow through the pond is considered.

62. The NSE and PBIAS values for the Georgia site were much more negative generally than those for the North Carolina site, suggesting the model deviates more from observed values in Georgia than North Carolina. On the other hand, the R^2 values for the Georgia site were comparable or larger than values for the North Carolina site. The lower NSE values and larger negative PBIAS values at the Georgia site may be due to the grassed waterway at the site. However, the data are insufficient to reach this conclusion.

63. The statistical analysis of the EFED model performance at both the North Carolina and the Georgia monitoring sites indicates the model performs very poorly. Based on statistical values used by hydrologic/water quality modelers, there is no possibility of the model performance being considered to perform "reasonably well" or "quite well" as the EFED concludes. The only conclusion that should be reached for the EFED models is that they do not perform well. It does not inform the exposure analysis better than the mean of the available field data and should not be used to predict future trends.

F. EFED's Models Should Be Improved as a Long-Term Objective.

64. EFED's effort to improve the representation of pond conditions by considering variable volume (flow through the pond) in the model is a step in the right direction. Model performance was so poor, however, that the statistics do not indicate the model's ability to simulate the monitored data was improved as compared to the model that did not consider variable volume. Further refinements are needed for representation of reality. Comparison of the modeled concentrations with observed data indicate a significant over-prediction of observed data. Continued refinement in representation of agricultural production and water systems within the model is consistent with EFED's tiered modeling approach.

65. For some locations and situations, the current modeling approach does not represent situations that are ecologically relevant. For example, modeling small ponds in arid regions such as the Central Valley in California that dry up and using constituent concentrations at time steps shortly before the ponds become dry do not represent situations that are of ecological relevance given the severe stresses on the aquatic systems due to the ponds becoming dry. Such ponds are unlikely to even exist given irrigation management practices.

66. Pore water data are critical to assessing the impacts of flubendiamide and des-iodo in the environment. In general, pore water concentrations of constituents in the environment are not widely studied, which is reflected in little scientific literature on this issue. Additional study of pore water concentrations of constituents, including those of concern in this report, are needed. Further, few models that predict pore water concentrations are available, and those that are available have not been widely tested. Additional study of pore water and its constituents is needed as is the further development and testing of models for predicting pore water constituents.

G. Monitoring Results Show That Flubendiamide and Des-Iodo Have Not Accumulated to Levels of Concern.

67. Because the EFED model does not accurately estimate flubendiamide and des-iodo concentrations, it is not useful in assessing expected des-iodo concentrations to support a science-based risk assessment. Thus, EFED should rely on the available monitoring data only in reaching its regulatory determinations. The best available monitoring data for exposure or risk evaluation come from the North Carolina and Georgia pond studies, where both water column and pore water concentrations were measured with product usage confirmed in the adjacent field. The following table (Table 3) compares the toxicity endpoints identified by EFED and Bayer (as summarized in EPA's risk assessment documents) to the maximum values observed in each

location for the Bayer monitoring study. The USGS data are included in the summary table for comparative and confirmatory purposes.

Table 3. Maximum observed flubendiamide and des-iodo concentrations compared to toxicity endpoints.

Water Body		Water Column <u>maximum</u> concentration, ppb		Pore Water <u>maximum</u> concentration, ppb	
	Sampling	**Flubendiamide**	**Des-iodo flubendiamide**	**Flubendiamide**	**Des-iodo flubendiamide**
Toxicity Endpoints (NOEC / NOAEC)	*EFED*	*15.5*	*1.9*	*1.5*	*0.28*
	Bayer	*33*	*4.0*	*2.6*	*19.5*
Pond	Pond Studies	1.95	0.32	0.30	0.10
Intermittent Stream		0.62	0.05	0.19	0.17
Perennial Stream/River		0.09	0.01	0.19	0.05
Stream / River	USGS	0.93	0.07	not sampled	not sampled

Bayer NC and GA pond studies sampled monthly for 4.5 years ; USGS – 5,004 samples from national monitoring network, over 3 years, approx. monthly (not all sites for full duration)

68. As shown in Table 3, the maximum observed concentrations of flubendiamide and des-iodo in ponds, intermittent streams, and perennial streams in the water column and the pore water are all below the endpoints identified by EFED and Bayer. The real-world data, including more than 1,000 overlying and pore water pond samples, do not show any concentrations indicating accumulation to or near identified toxicity endpoints.

69. As Dr. Moore explains in his declaration, the critical factor driving EPA's cancellation decision is EPA's determination that des-iodo levels in pore water will increase beyond the 0.28 ppb endpoint that EPA has identified. As Dr. Moore further explains, EPA's reliance on the 0.28 ppb level of concern derived from the spiked water study is not scientifically sound, and the more relevant and scientifically sound endpoint is the 19.5 ppb level of concern from the spiked sediment study. As shown in the table above, after almost five years of product use in pond settings similar to EFED's modeled pond scenario, not a single sample has exceeded even the incorrect 0.28 ppb level of concern.

70. The maximum measured concentration of des-iodo in pore water was 0.17 ppb, which is below EPA's incorrect 0.28 ppb level of concern, and 115 times lower than the proper 19.5 ppb des-iodo pore water level of concern based on the spiked sediment study. The maximum 0.17 ppb pore water concentration was measured at a single site, with concentrations decreasing in subsequent sampling taken at the same site. Moreover, out of 509 pore water samples from Bayer's monitoring studies, only five samples were measured at or above 0.10 ppb.

H. Monitoring of Flubendiamide and Des-Iodo Concentrations Should Continue.

71. Given the currently available data and the poor performance of the current models in explaining monitored data, data collection efforts should continue. Currently, the mean of the data is a better predictor than EFED's models of actual observations in the Bayer monitoring sites. While the data do not suggest that flubendiamide or des-iodo is accumulating to levels of concern, continuation and potential expansion of the monitoring studies would provide the most reliable data on this question. It is my opinion, therefore, that the monitoring study should continue for perhaps 2-4 additional years and expansion to additional sites should be considered.

72. If the monitoring is continued for a sufficiently long period, I would expect concentrations in the pond sediment and pore water to eventually reach a plateau resulting from the dynamic equilibrium of residues entering and leaving the watershed as described above and confirmed by the monitoring data available to date.

73. The USGS data set for flubendiamide and des-iodo in streams and rivers continues to grow. This data set should continue to be explored to understand the concentrations of flubendiamide and des-iodo under actual conditions as well as their spatial and temporal

distribution. Data from other sources may also be available that provide insight into the concentrations and distributions of these constituents in the water environment.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 11th day of April, 2016

Bernard Engel